THE EFFICACY OF CHIROPRACTIC ADJUSTMENT IN THE TREATMENT OF PRIMARY METATARSALGIA

BY

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I, Shayan Lian Petersen, do hereby declare that this dissertation represents my own work both in conception and execution.

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DEDICATION

To my Mother, who has shown me the meaning of strength, perseverance and love.

To my Father, who has always believed in my ability to achieve my greatest ambitions.

To Ivor, a special gift in my life, for the past five years.
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ABSTRACT

The purpose of this investigation was to investigate the relative efficacy of foot and ankle adjustments as opposed to placebo ultrasound, in terms of subjective and objective clinical findings, in the treatment of primary metatarsalgia.

This was a randomised, controlled, clinical trial consisting of two groups. Group A received foot and ankle adjustments, while Group B received detuned ultrasound as the placebo treatment. Each group consisted of twenty subjects between the ages of 20 and 78 years, who were randomly assigned to their respective groups. It was hypothesised that foot and ankle adjustments would be effective in the treatment of primary metatarsalgia. Subjects diagnosed with primary metatarsalgia were included in the study.

The treatment regime consisted of a course of eight treatments, with two treatments a week, spread over a four-week period. Subjective and objective measurements were taken at the initial, second, third and final consultations. Subjective data consisted of the short-form McGill Pain Questionnaire, the Numerical Pain Rating Scale – 101 and the Foot Function Index. Objective data was collected by means of Algometer measurements.

Inter-group comparisons were made using the non-parametric Mann-Whitney unpaired U-test for the categorical variables and the parametric two-sample unpaired t-test for the continuous variables. Inter-group comparisons of the subjective readings showed that the two groups were similar at the beginning of the study, except in terms
of their perception of “worst” pain, where the two groups differed significantly. Group A was less affected by pain subjectively than Group B. There was found to be a significant statistical difference between the subjective measurements at the end of the treatment period, with Group A experiencing greater benefit. Algometer readings (objective data) showed a statistically significant difference between the two groups, only in terms of pressure-pain tolerance, at the final consultation. Group A had the higher pain tolerance.

For the intra-group comparison, the non-parametric Wilcoxon’s signed rank test was used for the categorical variables, and the two-sample paired t-test was used for the continuous variables. From the results of the intra-group analysis, it was revealed that both groups subjectively shared a statistically significant improvement overall, by the end of the respective treatments. However, Group A responded statistically significantly earlier in the program, as opposed to Group B. Objectively, Group A appeared to show a significant statistical improvement during the treatment period, but this was not the case in Group B.

It can be noted that subjectively and objectively, foot and ankle adjustments appears to be a reliable treatment of primary metatarsalgia, and that foot and ankle adjustments appears to be more effective than placebo in the treatment of primary metatarsalgia.
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DEFINITION OF TERMS

Primary Metatarsalgia –

Generalised pain in the forefoot under the area of the metatarsal heads (Jahss 1982: 1273).

Fixation –

Lack of movement of a joint (Gatterman 1990: 408).

Motion Palpation –

A palpatory diagnostic procedure utilised to assess the character of the motion of a motion unit, to determine if a motion dysfunction exists (Nook 1998: 28).

Chiropractic Manipulative Therapy (CMT) –

Manipulation or adjustment of a joint, in order to remove fixations therein and restore normal movements to the joint (Hammond, S.L. 1999). This includes foot and ankle adjustments.

Placebo –

A procedure with no intrinsic therapeutic value, done to satisfy the patient’s symbolic need for therapy (Dorland’s 1995: 638).
Subjective Data –

For the purpose of this study, this refers to data that was recorded as personally perceived by the patients i.e. how they felt with regard to pain and disability (Hammond, S.L. 1999).

Objective Data –

For the purpose of this study, this refers to data that was noted by the researcher i.e. physical change that were noted by means of an algometer (Hammond, S.L. 1999).
CHAPTER ONE

THE PROBLEM AND ITS SETTING

1.1 PROBLEM STATEMENT

The purpose of this randomised, placebo-controlled study is to determine the efficacy of Chiropractic manipulation of the foot and ankle in terms of objective measurements and subjective measurements in order to determine what contribution such intervention makes in the management of primary metatarsalgia.

1.2 SUB-PROBLEMS

1.2.1 SUB-PROBLEM 1

The first sub-problem is to evaluate the effectiveness of foot and ankle joint manipulation used to treat the experimental group, in terms of objective and subjective measurements in order to establish the value of treating primary metatarsalgia with foot and ankle manipulation.

1.2.2 SUB-PROBLEM 2

The second sub-problem is to evaluate the effectiveness of detuned ultrasound used to treat the control group, in terms of objective and subjective measurements in order to establish the value of detuned ultrasound in the treatment of primary metatarsalgia.
1.2.3 SUB-PROBLEM 3

The third sub-problem is to integrate the results obtained from the experimental group and control groups in order to determine what contribution chiropractic manipulation of the foot and ankle makes, as opposed to detuned ultrasound, in the management of primary metatarsalgia.

1.3 HYPOTHESES

1.3.1 THE ALTERNATIVE HYPOTHESIS

It is hypothesized that manipulation of the foot and ankle joints for the treatment of primary metatarsalgia, will in terms of subjective and objective measurements provide relief of pain.

1.3.2 THE NULL HYPOTHESIS

It is hypothesised that detuned ultrasound for the treatment of primary metatarsalgia will have little or no effect in terms of subjective and objective measurements.

1.4 IMPORTANCE OF THE STUDY

Metatarsalgia, described as generalised pain in the forefoot under the area of the metatarsal heads, is one of the most common disorders of the adult foot (Jahss 1982: 1273). Jahss (1982: 1239) also describes it, as one of the most frequent sources of pain in the human body and it is a common foot complaint amongst the elderly (Matheson et al. 1989, and Levy, L.A and Hetherington, V.J. 1990: 563).
Surgery is also an option for the treatment of primary metatarsalgia and this usually involves metatarsal osteotomies. However, metatarsalgia is described as a lesion symptom complex (Jiminez et al. 1990); referring to the multi-faceted pathomechanics of the condition, which are poorly understood. Because of this, many complications result from metatarsal osteotomies. Based on this, Jahss (1982: 1274) recommends non-operative measures first to see if pain can be improved or alleviated.

Current treatment methods are centred mainly on orthotic devices designed to decrease pressure in the area of the metatarsal heads. However, orthotics come at a considerable cost and there is essentially no objective evidence of their efficacy (Holmes and Timmerman 1990).

Other treatment options include analgesics, non-steroidal anti-inflammatories (NSAIDS), local steroid injections (Levy, L.A. and Hetherington, V.J. 1990: 564) and low-dye taping (Scranton et al. 1982). Apparently no clinical controlled trials are available on the efficacy of the above. These techniques, in the author’s opinion, do not seem to satisfactorily address the biomechanics and joint pathomechanics of metatarsalgia.

This study will attempt to determine the effectiveness of chiropractic manipulation in the treatment of primary metatarsalgia, thereby providing a solution to the problem. Certain health benefits may be apparent if the treatment was demonstrated to be effective, such as delaying, or removing the possibility of surgery; thereby reducing
cost and possible risk to the patient. The results will also provide direction and information to practising health professionals.

Jahss (1982: 1253), an orthopaedist and the author of a text for foot and ankle care, states that manipulation is fundamental in the treatment of primary metatarsalgia, principally at the level of the metatarsophalangeal joint. Subotnik (1989: 247), a doctor of podiatric medicine who went on to qualify as a chiropractor, suggests manipulation for metatarsalgia, even if surgery is required, to decrease secondary fibrositis from spasm and joint dysfunction. These views are not supported in the literature, but strongly suggest the need for research into the efficacy of chiropractic manipulation in the treatment of primary metatarsalgia.
CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

Primary metatarsalgia, described as generalised pain in the forefoot under the area of the metatarsal heads, is one of the most common podiatric complaints presenting to the podiatric physician (Jiminez, A.L. et al. 1990). It is also reported to be one of the most perplexing diagnostic problems in podiatry (Pack, L.G. and Julien, P.H. 1990). The symptoms associated with it range from mild to incapacitating.

2.2 EPIDEMIOLOGY


In a retrospective study by Matheson et al. (1989), patient data was obtained from an outpatient sports medicine clinic over a five-year period. The clinical presentation of overuse injuries in older and younger athletes was compared. A total of 1 407 cases were studied, with the average “old” age group being 56,9 +/- 6,1 years and “young” being 30,4 +/- 8,1 years. The injuries included: tendinitis, plantar fascitis, metatarsalgia, meniscal injury, patella-femoral pain syndrome and stress fracture or periostitis. The frequency of metatarsalgia was found to be more common in the older
age group. In the author’s opinion, this study has the benefit of a large sample size, which should give a good indication of the prevalence of metatarsalgia and in which age group. However, this is a study of athletes alone so it is not a true reflection of the prevalence of metatarsalgia in the general population; with influential factors, such as obesity.

Marti et al. (1988) conducted a survey on the epidemiology of running injuries. Information pertaining to the incidence, site and nature of jogging injuries among all participants of a popular 16km race was obtained. Although the sample size was large at 4 358 subjects, they were all male, which in the authors opinion is not a true reflection of epidemiology. The prevalence of middle foot, toes and sole injuries was 3.2%, 1.8% and 3% respectively. Metatarsalgia may be included in this area of injury, but the survey does not state this.

Shekelle and Brook (1991) conducted a community-based study on the use of chiropractic services. Data from a prospective large-scale community-based population (5 279 subjects) was analysed in terms of their response to various questions, including; “for what symptoms do they seek care?”. Orthopaedic foot problems were found to be a mere 1.1% of reasons for visiting a chiropractor. This in itself is enough of an incentive to increase public awareness of chiropractic scope of practice by doing research into this area.

The literature, to date, contains very little information on the demographics and epidemiology of metatarsalgia.
2.3 ANATOMY AND BIOMECHANICS OF THE METATARSOPHALANGEAL JOINT

To effectively recognise and treat pathologies at the metatarsophalangeal (MTP) joints, it is important to understand the normal anatomy and biomechanics of these joints.

2.3.1 ANATOMY

The MTP joints are ovoid or ellipsoid; they are formed by the rounded heads of the metatarsal bones, which fit into the shallow cavities on the bases of the proximal phalanges. They are situated approximately 2.5cm proximal to the webs of the toes.

The articular cartilage covers the distal and plantar surfaces of the heads of the metatarsal bones. However, it does not extend onto the dorsal surfaces of the metatarsal heads (Gray, H. 1980: 499-500).

The ligaments of the joints are capsular, plantar, deep transverse metatarsal and collateral.

The fibrous capsules surround the joints and are attached to the margins of the articular surfaces. Dorsally, they are thin and may be separated from the tendons of the long extensors by small bursae: they are inseparable from the deep surfaces of the plantar and collateral ligaments (Gray, H. 1980: 499-500).
The deep transverse metatarsal ligaments consist of four short, wide, flattened bands, which connect the plantar ligaments of adjoining MTP joints to one another. Their dorsal surfaces are related to the interossei and their plantar aspects to the lumbricals and the digital vessels and nerves. They are connected to the plantar ligament of the first MTP joint (Gray, H. 1980: 499-500).

The plantar ligaments are thick, dense, fibrous structures. They are placed on the plantar surfaces of the joints in the intervals between the collateral ligaments, to which they are attached; they are loosely united to the metatarsal bones, but are firmly connected to the bases of the proximal phalanges. Their margins are continuous with the deep transverse metatarsal ligaments, and their plantar surfaces are grooved for the flexor tendons, the fibrous sheaths of which are connected to the sides of the grooves. The deep surfaces of the ligaments form parts of the articular facets for the heads of the metatarsal bones (Gray, H. 1980: 499-500).

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The collateral ligaments are strong, rounded cords, on each side of each joint. Each is attached by one end to the dorsal tubercle on the side of the head of the metatarsal bone, and runs obliquely forwards and downwards to reach the corresponding side of the base of the phalanx (Gray, H. 1980: 499-500).

Movements at the joints include:

Flexion (30-40 degrees) is produced by flexor digitorum brevis, lumbricals and interossei, assisted by flexor digitorum longus and accessories muscles. In the little
toe, the flexor digiti minimi brevis assists and in the great toe, the flexor hallucis longus and brevis are the only muscles concerned (Gray, H. 1980: 499-500).

Extension (50-60 degrees) is produced by the extensor digitorum longus and brevis, and the extensor hallucis longus (Gray, H. 1980: 499-500).

Adduction of the great toe is produced by adductor hallucis; of the third, fourth and fifth toes, the first, second and third plantar interossei respectively (Gray, H. 1980: 499-500).

The abductor hallucis muscle produces abduction of the great toe. Movement of the second toe, to the medial and lateral sides, is performed by the first and second dorsal interossei respectively. Movement of the third and fourth toes, is carried out by the corresponding dorsal interossei. Lastly, abduction of the little toe is done by the abductor digiti minimi (Gray, H. 1980: 499-500).

If the foot is cut transversely at the level of the metatarsal heads, the following can be seen (refer to diagram on page 10): 1) the metatarsals, 2) sesamoids, 3) extensor hallucis longus tendon, 4) flexor hallucis longus tendon, 5) extensor tendon of the toe, 6) flexor tendon of the toe, 7) interosseus muscles, 8) lumbricals, 9) blood vessels, 10) nerves, 11) deep plantar aponeurosis, 12) superficial plantar aponeurosis. (Jahss 1982: 1233).
2.3.2 BIOMECHANICAL CONSIDERATIONS

Biomechanical considerations are important in the proper evaluation of metatarsalgia (Jiminez, A.L. et al. 1990).

On weight bearing, the forefoot must compensate in the frontal plane during the stance and propulsive phases. This frontal plane compensation is derived from two sources (Hicks, 1953). The first source is by the longitudinal axis of the midtarsal joint, which allows for frontal plane motion within the midfoot to adapt the forefoot to an uneven terrain. A second source is the individual range of motion of the metatarsals, mainly dorsi and plantarflexion.

The first metatarsal articulates with the medial cuneiform and normally has the greatest range of motion of the metatarsals. The second and third metatarsal ranges of motion are relatively small compared with the first metatarsal. There is very little
dorsiflexory motion of the second and third rays, so during the stance phase of gait, the second and third rays can exhibit very little accommodation. Normally the third ray is more rigid than the second and the majority of its motion is plantarflexory. This occurs during propulsion as the second and third digits dorsiflex (Jimenez, A.L. et al. 1990).

The fourth metatarsal has a relatively greater range of motion, with greater dorsiflexory motion as compared with the second and third metatarsals, allowing for accommodation during the stance phase of gait (Jimenez, A.L. et al. 1990).

The fifth ray is normally the second most mobile (the first being the most mobile). Its range of motion is independent of the other lesser metatarsals. The motion is triplane; however, it is mostly dorsiflexory and plantarflexory, thus allowing the fifth ray to accommodate for pressures in the frontal plane (Jimenez, A.L. et al. 1990).

Any structural or biomechanical abnormality will alter the pressures under the metatarsal heads, possibly resulting in metatarsalgia, hyperkeratotic lesions or both (Jimenez, A.L. et al. 1990).
2.4 AETIOLOGY AND PATHOLOGY OF METATARSALGIA

2.4.1 GENERAL CONSIDERATIONS

The cause of metatarsalgia can be classified into three large groups. The first is due to localised disease in the region, for example Morton’s neuroma. The second is due to alteration of fine biomechanics in the forefoot. Finally, the third group is pain due to systemic diseases, with symptomatology in the forefoot region (example, rheumatoid arthritis) (Jahss, M.H. 1982: 1239).

By far the most common is biomechanical alterations, which can be either structural or functional in origin (Jahss, M.H. 1982: 1239). Biomechanical alterations can be divided into the following groups:

A. Overload of anterior support

a. Due to the heel of the shoe being too high

The result is overload of the forefoot (Jahss, M.H. 1982: 1240).

b. In the equinus foot

There is decreased dorsiflexion of the ankle, either due to congenital abnormalities, or a shortened achilles tendon. The result is overload of the forefoot (Jahss, M.H. 1982: 1240).
c. In the cavus foot

There is an abnormal increase in the plantar arch, resulting in the metatarsals being too vertical to the horizontal surface. This gives rise to increased forefoot pressure (Jahss, M.H. 1982: 1240).


B. Irregular distribution of metatarsal load (Jahss, M.H. 1982: 1248)

a. First ray overload syndrome

First ray overload syndrome occurs in two scenarios: a) a long big toe with a long metatarsal. During gait, the toe rubs against the point of the shoe causing retrograde pressure on the first MTP joint. This predisposes to osteoarthritis of the joint. b) With frontal load imbalance in the foot. This results in the first metatarsal and the sesamoids supporting excess pressure. Sesamoiditis may occur.

b. Central ray insufficiency syndrome

When there is a pathologically high anterior arch of the forefoot, there is an increase in pressure on the first and fifth metatarsals, due to the lack of weight bearing by the other metatarsals. The condition may be congenital, iatrogenic or neurological in nature.
c. Overload of central ray syndrome

Overloading of the central rays commonly involves more than one metatarsal. Most often they are affected in diminishing order from the second to the fourth metatarsal. This usually occurs as a result of an insufficiency of the first ray. A metatarsal, which is affected on its own results from either: a) an increased metatarsal length compared to its neighbours; b) an increased metatarsal angle to the horizontal surface; c) loss of dorsiflexion of the tarsometatarsal joint, especially common in the fourth ray.

d. First ray insufficiency syndrome

This refers to a lack of support in the first ray. This may result in splay foot or dropping of the anterior arch, which predisposes to the overload of the second and third rays.

2.4.2. STRUCTURAL AETIOLOGIES

a. Metatarsal length pattern

The most common metatarsal length patterns are: 2>3>1>4>5, 2>1>3>4>5 and 2>1=3>4>5 (Jiminez, A.L et al. 1987: 57-113). Any deviation from these length patterns is likely to result in pressure differences in the forefoot, predisposing it to problem areas.
The second, or the second and third metatarsals are the ones that are commonly long. This often predisposes to crowding of these toes in the shoe, resulting in contractures at the proximal interphalangeal joint. This creates excessive plantarflexion of the metatarsal head, so worsening the symptoms.

Brachymetatarsia is a shortened ray, either due to congenital, iatrogenic, traumatic or infectious reasons. This results in increased pressure being placed on neighbouring metatarsal heads, possibly giving rise to symptomatology. The congenital form is the least likely to give rise to symptoms, possibly due to the body adapting to the anomaly (Jiminez, A.L. 1979).

b. Localized Metatarsal Equinus

This involves an excessively plantar flexed metatarsal. It is a rare condition and the cause is often the retrograde force of a contracted digit, resulting in the excessive plantar flexion of the metatarsal (Jiminez, A.L et al. 1990).

c. Osteochondritis

Osteochondritis is a developmental avascular necrosis of the metatarsal head. This occurs most often in the second decade of life, and it most frequently involves the second metatarsal. Excessive plantar flexion creates an avascular condition due to chronic compression of the epiphysial plate of the metatarsal head (Jiminez, A.L et al. 1990).
d. Hypertrophic Metatarsal Condyles

The development of hypertrophic metatarsal condyles usually occurs in elderly patients and may cause excessive submetatarsal pressure resulting in metatarsalgia (Jiminez, A.L et al. 1990).

e. Iatrogenic Metatarsalgia

Iatrogenic metatarsalgia is usually caused by excessive shortening or elevation of a metatarsal, resulting in increased pressure being placed on adjacent metatarsal heads. This creates what is known as transfer lesions (Jiminez, A.L et al. 1990).

f. Anterior Fat Pad Thickness

Fat pad atrophy predisposes the metatarsals to increased direct pressure, especially in people of advanced age and athletes (Hyde, H.E. and Gengenbach, M.S. 1997: 499).

2.4.3 FUNCTIONAL AETIOLOGIES

a. Cavus Foot

The cavus foot involves either a forefoot equines or a structural plantarflexory deformity at the navicular-cuneiform joint, or Chopart's joint. The severity of metatarsalgia is dependant on the degree of plantar flexion of the metatarsals and the amount of compensation present at the ankle, subtalar and midtarsal joints (Jiminez, A.L et al. 1990).
Associated with the increased plantarflexion of the metatarsals, in relation to the weight-bearing surface, is the retrograde buckling of the MTP joints. This worsens the metatarsalgia. Common to the anterior cavus foot are claw toes, which often leads to severe metatarsalgia (Jiminez, A.L et al, 1990).

b. Varus and Valgus Deformity

Severity of metatarsalgia will depend on the level of patient activity and the degree of forefoot compensation for the varus or valgus deformity. Varus deformity will predispose to metatarsalgia under the fourth and fifth metatarsals and valgus deformity to metatarsalgia under the first to third metatarsals (Jiminez, A.L et al, 1990).

c. Hypermobile Pathological Flat Foot with Hallux Abducto Valgus and Hypermobile First Ray

A lesion is often present under the second metatarsal in this condition. In this foot, the first metatarsal dorsiflexes in midstance and the propulsive phase of gait. The midtarsal joint unlocks and the peronius longus cannot stabilize the first ray because its pull is from an unstable fulcrum at the cuboid, so the second metatarsal bears the brunt of the weight, creating symptoms (Jiminez, A.L et al, 1990).
d. Equinus

It is important to correctly evaluate the gastrocnemius, gastrosoleus and ankle joint, as they all can create excessive pronatory forces resulting in metatarsalgia (Jiminez, A.L et al. 1990).

2.5 EVALUATION OF PRIMARY METATARSALGIA

The history of metatarsalgia is typically of insidious onset and gradual progression, aggravated by weight bearing activity and relieved by rest (Oloff, L.M. 1994: 236). Shoes and soft surfaces are often better than barefoot.

Evaluation of a patient with metatarsalgia must include a thorough biomechanical evaluation of the foot and ankle (Appendix 3), including the assessment of vascular and neurological status. This evaluation is vital in outlining the aetiology of the condition (as discussed in 2.4).

Metatarsalgia can present as pain on the dorsal aspect of the metatarsals, plantarly, at the MTP joint or in the interspace (Pack, L.G. and Julien, P.H. 1990). Generally, rheumatological conditions present with pain dorsally, whilst biomechanical factors cause plantar pain. Associated may be bursitis or capsulitis, especially with claw toes. Biomechanical causes of metatarsalgia resulting increased pain with weight bearing and decreased pain with rest. Increased pain and stiffness in the morning, which
Causes of secondary metatarsalgia are important differential diagnoses of primary metatarsalgia. These include avascular necrosis of the metatarsal head (Freiberg's disease), subluxation and dislocation of the MTP joint, metatarsal stress fracture, interdigital nerve entrapment (Morton's neuroma), plantar forefoot neuritis, plantar bursitis, distal plantar fascitis, growth plate injury in children, tarsal tunnel syndrome, vascular abnormalities, inflammatory joint disease and peripheral neuropathy (Oloff, L.M. 1994: 236).

2.6 MEDICAL MANAGEMENT OF METATARSALGIA

2.6.1 NON-Steriodal Anti-Inflammatory Drugs (NSAIDS)

The NSAIDS have analgesic, anti-inflammatory and anti-pyretic properties. The action of NSAIDS is interference with the conversion of arachidonic acid to enzymes associated with inflammation, by acting as mediators of the inflammatory response, including prostaglandins, thromboxane and prostacyclins.

There is controversy surrounding the effectiveness of NSAIDS. A number of studies on the effectiveness of NSAIDS in the management of acute soft tissue injuries, have been reviewed by Clyman (1986) and Almekinders (1990). Most of the studies lacked
a placebo group and compared one NSAID to another. Of the eight well-designed studies, which included placebo and studied one type of ligament injury, only four of the studies showed a significantly better outcome in the treatment group than the placebo group (Almekinders 1990). As for results, the precise criteria for the use of NSAIDS in the management of injuries remain a matter of debate.

There are a large number of NSAIDS available, but the various clinical trials have failed to show that any one NSAID is consistently better than another is.

In general, the NSAIDS are safe drugs with minimal serious side effects, particularly in view of their widespread use. The most common side effects involve the gastrointestinal tract, especially gastric pain, nausea, indigestion and heart burn (Zuluaga, M. et al. 1995: 730). The newer drugs do have an enteric coating which decreases these side effects. The incidence of gastric ulceration with short-term use is rare, but gastric bleeding, particularly occult bleeding, does occur and may contribute to iron deficiency. Other side effects include asthma, allergic rhinitis, rashes, tinnitus, deafness, headache and confusion; but these are unusual.

NSAIDS do have a number of important drug interactions. Interactions have been reported with anti-coagulants, anti-hypertensives, diuretics and peripheral vasodilators. These must be taken seriously as they are common drugs used amongst people in the fifth decade of life and older and it is in this population group that metatarsalgia is most prevalent (Zuluaga, M. et al. 1995: 730).
2.6.2 ANALGESICS

Analgesics, commonly known as painkillers, are widely used.

Aspirin, paracetamol and codeine are the most common analgesics. Aspirin has an analgesic effect at doses of 250-300mg. At higher doses, aspirin also has an anti-pyretic effect, but the incidence of side effects increases proportional to the dose increase. Aspirin and paracetamol both have an anti-pyretic effect, but paracetamol has no influence on the inflammatory process (Zuluaga, M. et al., 1995: 729).

Codeine is a more potent analgesic, as it is a narcotic analgesic; meaning it causes a reversible depression of the central nervous system, which is marked by stupor or insensibility (Dorland 1995:539).

2.6.3 CORTICOSTEROID INJECTION

Corticosteroids are synthetic equivalents of the steroids produced by the adrenal cortex (excluding sex hormones). They function as anti-inflammatory agents and suppress the immune response (Dorland 1995: 196). Local injection of corticosteroids into the MTP joint minimizes the risk of side effects associated with systemic administration of the drug, but it does however remain controversial (Zuluaga, M. et al., 1995: 731), especially into weight-bearing joints.
The effects of the injection may be dramatic, but may have side effects such as the inhibition of normal collagen synthesis and thus interference with the tissue repair process (Zuluaga, M. et al. 1995: 730). The steroids may mask the protective pain mechanism and lead to the patient overusing the damaged joint and so lead to increased degenerative changes.

The main side effect remains infection, however this is rare if proper aseptic techniques are adhered to, especially with intra-articular injections (Zuluaga, M. et al. 1995: 730).

2.6.4 METATARSAL PADS AND INSOLES

The treatment of metatarsalgia secondary to the plantar prominence of the metatarsal heads has lead to the development of numerous orthotic devices designed to decrease pressure in these areas (Holmes, G.B. and Timmermann, L. 1990). There is however little objective evidence to their efficacy.

In a randomised control trial by Holmes and Timmermann (1990), the effect of simple metatarsal pads on pressures transmitted to metatarsal heads was measured. Quantitative measurements of dynamic peak pressures for ten asymptomatic subjects, with and without metatarsal pads, were taken using the pedobarograph. The sample size was small at ten subjects, and they were also asymptomatic, which may produce altered data to a symptomatic group.
Female volunteers had a reduction in peak metatarsal pressures from 12% to 60% when a small metatarsal pad was appropriately applied to the foot. In two of five males, there was a decrease in metatarsal pressure of 14% - 44%. One male had no change in pressure, while two others had an increase in pressure from 8% to 28%. Although metatarsal pads are inexpensive, and when appropriately positioned can be beneficial, there is no extensive evidence to their benefit. The greatest relief seems to be amongst the female patients.

In a study by Chang et al. (1994) to assess the changes in the plantar pressure metrics resulting from metatarsal pad use, ten normal adult male patients were used. Their findings of alterations in peak pressure in this study were consistent with the findings in the study by Holmes and Timmermann (1990), in which subjects differed in outcomes with metatarsal pad use. Importantly, Chang et al. (1994) found that the redistribution in pressure metrics came at a cost of a significant increase in pressure in the metatarsal shaft region.

A prospective randomised controlled trial comparing the effectiveness of two ready-made insoles in the treatment of lesser metatarsalgia showed that the one was better than the other in terms of reduction of peak metatarsal pressure (Kelly, A. and Winson, I. 1998). However, no placebo group was involved. In the study, the Lange Blue Line insole (plastizote foam) was found to be more effective than the Bauerfiend Viscoped insole (silicone) in terms of symptom relief. The Viscoped insole was selected for the study in the hope that an off-the-shelf insole would reduce the orthotist time required for the management of this relatively common problem. This,
however, was not proven to be true, so orthotics still remain a fairly costly form of treatment.

In a study by Poon and Love (1997), fourteen symptomatic metatarsalgia patients were assessed in terms of the frequency of the use of foot orthotics (custom-made) and their efficacy in reducing plantar pressures. 90% used their orthotics all or most of the time. There was a mean reduction of 71% in the visual analogue scale pain score as well as a mean reduction of 13% in the plantar pressure as measured by the F-scan pedobarograph. They concluded that although the study was small and more research was required into this area, patients do obtain significant symptomatic relief from custom-made insoles. However, there still remain problems with accurate construction and placement of orthotics in the shoe.

No evidence is available to suggest that metatarsal pads or orthotics are better than placebo.

2.6.5 **LOW-DYE TAPING**

In a pilot study by Scranton *et al.* (1982) involving five asymptomatic subjects, the effect of low-dye taping on forces under the foot during gait was examined. Taping was seen to cause a shift in forces anteriorly to the forefoot much more rapidly and was therefore expected to aggravate metatarsalgia symptoms. However, the taping significantly diminished the duration of forces under the midfoot, so is more
beneficial for conditions such as plantar fasciitis. A Cholesterol crystal force plate analysis and a computerized kistler force platform were used in the study.

2.6.6 SURGERY

Operations on the metatarsals for metatarsalgia are generally aimed either to shorten the metatarsal or to elevate the plantarflexed metatarsal head, and by so doing, it is hoped, to relieve the pressure that may be causing metatarsalgia (Jahss, 1982: 1274). Jahss also suggests that since evaluation methods are imprecise at best, it may be better to treat metatarsalgia patients with non-operative measures if possible, to see if pain can be improved or alleviated.

Lesser metatarsalgia surgery has been associated with many complications (Jiminez, A.L. et al. 1990). The most common complication being recurrent or transfer lesions. Recurrent lesions occur when the metatarsal head is not sufficiently elevated or when the true cause of the lesion is not correctly identified or addressed. Transfer lesions are noted beneath adjacent metatarsals when a metatarsal is overcorrected in dorsiflexion. Another common complication is non-union at the osteotomy site.

Less common complications include avascular necrosis of the lesser metatarsals due to lack of revascularization of the head. Floating toe syndrome is another. This occurs when there is relaxation of the plantar capsular structures and plantar fascia, and results in a lack of loading of the toe during midstance and propulsion. The dorsal structures then become tighter causing the digit to retract, causing a floating toe.
The fact that there are such a large number of procedures performed to alleviate the symptoms of metatarsalgia suggests that the ideal procedure or treatment has not been discovered (Jiminez, A.L. et al. 1990).

2.7 MOTION PALPATION

2.7.1 INTRODUCTION

Within its anatomical range of motion, a normal joint exhibits in all planes of motion:

1. a large voluntary active range (used in voluntary exercise)

2. an involuntary stress-less passive range (used in mobilization)

3. a slight paraphysiological range that is determined by ligamentous plasticity, elasticity and visco-elasticity (used in adjustive techniques) (Schafer, R.C. and Faye, M.J. 1989: 11-12).

Specific, dynamic chiropractic adjustments are carried deep into the paraphysiological range, often to the anatomical limit, but the duration of the application of the maximum force is only a fraction of a second.

Abnormal motion is essentially any loss of motion that will interfere with proper function or will cause secondary pathological changes. Comparative examination of both feet may be of some assistance, although pathology of the feet is often bilateral (Jahss, M.H. 1982: 1255).
In a review of the available literature on the reliability of motion palpation, Gatterman (1990: 61) concluded that inter-examiner reliability for identifying motion or end feel restriction at specific segmental levels was poor. The fifteen studies Gatterman reviewed, however were only related to the spine i.e. five cervical, two thoracic, six lumbar and six sacroiliac.

2.7.2 MOTION PALPATION OF THE FOOT AND ANKLE JOINTS

In a preliminary study using twenty-one subjects with mechanical foot and ankle pain, inter-examiner reliability of palpation for foot and ankle joint tenderness was assessed (Brantingham, J.W. et al. 1995). In these subjects, palpation for joint tenderness of the foot and ankle was found to be a reliable examination tool (71.4% agreement).

Astrom and Arvidson (1995) conducted a study on 121 healthy subjects assessing alignment and motion in the normal foot. A standardized clinical assessment of ankle and subtalar joint motion, subtalar neutral, forefoot alignment, calcaneal stance, and the tibia to vertical angle was performed on each subject. None of the subjects conformed to the “ideal foot”, which appears to be rare. The authors suggested a reference based on clinical observations rather than theoretical considerations.

The foot and ankle joints are evaluated for normal range of motion and end feel. End feel and joint play are two separate terms. End feel is assessed at the end of passive range of motion and tests the integrity of the capsular and ligamentous fibers. Joint play is an accessory motion necessary for normal active and passive range of motion.
Joint play represents the amount of capsular laxity within a joint. If joint play is reduced, active motion will be decreased, restricted or abnormal, and may be painful (Gatterman, M.I. 1990: 98).

Joints and their motions, which are palpated in the foot and ankle, are listed in the foot and ankle regional examination (Appendix 3).

2.8 MANIPULATION OF THE FOOT AND ANKLE JOINTS

2.8.1 INTRODUCTION

Manipulation refers to mobilization and adjustments (Bergman, T.F. 1993: 124). Joint manipulative procedures are delivered to induce joint movement, thus their common application in the treatment of joint hypomobility (subluxation or dysfunction). When treating joint hypomobility, the adjustive thrust or mobilization is typically delivered in the direction of established joint restriction.

Clinical features of joint dysfunction are:

1. local pain: commonly changes with activity
2. local tissue hypersensitivity
3. altered alignment
4. increased, decreased or aberrant joint motion
5. altered joint play
6. altered end feel resistance

7. local palpatory muscle rigidity

2.8.2 TECHNIQUES AND USE

Jahss (1982: 1253) states that manipulation is fundamental, principally in the area of the MTP joints, in the treatment of metatarsalgia. He goes on to suggest that even if surgery is required for the treatment of metatarsalgia, manipulation is suggested in order to reduce the secondary fibrositis from spasm and joint dysfunction.

Manipulation for the treatment of metatarsalgia is extrapolated from studies by Brantingham et al. (1991) and Brantingham et al. (1994).

The first is a case report involving two cases of Morton’s neuroma, which is a perineurofibrosis of an interdigital nerve. It manifests as a burning pain, between the third and fourth metatarsals, that extends into the toes. The patients were treated with manipulation, various physiotherapy modalities, and/or orthotics, which resulted in a successful resolution of symptoms. However, this is a case report and various treatments were involved.

The second study was more comprehensive where twenty-nine patients with Morton’s neuroma were treated with chiropractic management. 83% of patients had moderate to excellent relief of pain from foot manipulation. Manipulation was applied to the MTP
joints, intermetatarsal joint, midtarsal and intertarsal joints and ankle mortise, depending on the presence of tenderness and stiffness detected on palpation. Diathermy and ultrasound were applied before manipulation and a metatarsal felt pad was placed beneath the second, third and fourth metatarsal heads. The multiple treatment protocol could have significantly affected the results, as the response to any one treatment alone was not known.

As there have been no studies to investigate the efficacy of chiropractic management of metatarsalgia, extrapolation for the treatment of metatarsalgia from the few studies on chiropractic treatment of Morton’s neuroma, although they in themselves are preliminary, is reasonable.

2.9 PLACEBO

Placebo ultrasound can have significant therapeutic psychological effects (Prentice, W.E. 1994: 276). Any treatment modality can act as a placebo, and the patient reactivity will vary according to the supposed potency of the treatment one thinks one is getting (Brody, H. 1980: 12). It is not always easy to distinguish placebo stimulus from active therapy, since cutaneous stimulation of any type may promote pain relief (Melzack, R. and Wall, P.D. 1965). The sham (detuned) ultrasound, which does involve skin contact over the area, cannot be considered to be physiologically inactive.
In a literature review by Brody (1980: 14-15), he looks at factors influencing the placebo effect. He found that a large number of patient variables, including age, sex, intelligence, and presence of neurosis and psychosis, have shown no correlation with regards to placebo response. One characteristic, which had been fairly consistent with influencing patient placebo reactivity, was stress or anxiety.

The usual placebo response is expected to be between 30% and 50% (Beecher, H.K. 1955).

2.10 SUMMARY

Metatarsalgia is a common condition, which can be very debilitating (Jahss 1982: 1239, 1273). It is a multifaceted and complex condition with the result that many forms of treatment have been developed, but none of them entirely successful on their own (Jahss, 1982: 1274). Although unsubstantiated, a multidisciplinary approach may be of benefit.

Anecdotal evidence suggests that chiropractic care may be of use in treating this condition, but no scientific evidence is available. The aim of this dissertation, therefore, was to further explore these observations to help clarify the role that chiropractic may play in the management of this condition.
CHAPTER THREE

MATERIALS AND METHODS

3.1. INTRODUCTION

This single blind, placebo-controlled study compared foot and ankle manipulation with the placebo management of primary metatarsalgia, over a four-week period.

3.2. PATIENT SELECTION

A sample size of forty primary metatarsalgia patients was used. These patients were recruited from the local Durban community by means of advertisements, posters and referrals. Patients responding to advertisements were screened to assess whether or not they fulfilled certain inclusion criteria.

3.3. INCLUSION AND EXCLUSION CRITERIA

Only patients who fulfilled the inclusion criteria, and had no exclusion criteria, were accepted into this study. This was determined at the initial consultation by the following procedure:

1) A detailed case history was taken (Appendix 1), and a cursory physical examination (page one, Appendix 2) done on each patient.
2) A foot and ankle regional examination (Appendix 3) was performed on each patient.

3) The researcher then explained the nature and importance of the study and each patient was then given the patient information sheet to read (Appendix 4).

4) Each patient then read and signed the Informed Consent Form (Appendix 5). Any questions they had were answered.

3.3.1 INCLUSION CRITERIA

The patients had two or more of the following (Ollof, L.M. 1994: 236):

1) Pain on joint compression or distraction
2) Pain on passive or active range of motion
3) Pain on active resistance to flexors or extensors
4) Pain on palpation of surrounding soft tissues

3.3.2 EXCLUSION CRITERIA

Exclusion criteria were secondary causes of metatarsalgia (Ollof, L.M. 1994: 236):

1) Avascular necrosis of a metatarsal head (Freiberg’s disease)
2) Subluxation and dislocation of the MTP joint
3) Metatarsal stress fracture
4) Interdigital nerve entrapment (Morton’s neuroma)
5) Plantar forefoot neuritis
6) Plantar bursitis
7) Distal plantar fascitis
8) Growth plate injury in children
9) Tarsal tunnel syndrome
10) Vascular abnormalities
11) Inflammatory joint disease
12) Peripheral neuropathy
13) Veruca

3.4 ALLOCATION OF THE SUBJECTS

Each patient was then allocated by random assignment, to one of two groups. This method involves two pieces of paper; one with Group A (experimental group- CMT) written on it and one with Group B (control group- Placebo) written on it.

The two pieces of paper were placed in a box. One piece was randomly drawn with the presentation of the first metatarsalgia patient, and that patient was allocated to the group written on the paper. Each subsequent patient was then allocated to the alternative group to which the previous patient was assigned (i.e. Group A, then Group B, then A, etc.). For blinding purposes, patients were not told to which group they were assigned.
3.5 TREATMENT INTERVENTIONS

Patients in the control group (Group B - Placebo) were treated using a detuned ultrasound machine. The machine was turned on, but set at zero Hertz of power, after which the ultrasound head was passed over the area of metatarsal tenderness, as determined by regional orthopaedic examination (Appendix 3).

Patients in the experimental group (Group A - CMT) were treated with foot and ankle adjustments of the fixated areas using Diversified Technique. Fixated areas were determined by incorporating motion palpation, joint challenge and local tenderness (Appendix 3), using the diversified technique.

The most commonly used adjustive techniques in this study were:

1) Intermetatarsal glide

2) Long axis distraction adjustments of the lesser metatarsaophalangeal joints (MTP) (second to fifth MTP joints).

3) Mortice separation

4) Anterior to posterior glide adjustments of the midtarsals

A detailed explanation of these techniques is available in Bergmann (1993: 702-722) and Michaud (1993: 135-145). For blinding purposes, the treatment was performed with the same amount of enthusiasm, and for approximately the same duration, in both groups.
Each patient received a total of eight consultations over a four-week period. This was based on the number of treatments recommended for Morton’s neuroma, by Brantingham et al. (1991). The authors recommended an average of four to nine treatments, for Morton’s neuroma, to obtain and maintain relief. All the consultations took place at the Technikon Natal Chiropractic Day Clinic.

3.6 METHODS OF MEASUREMENT

There are very few methods to measure metatarsalgia objectively. Therefore, both pressure-pain threshold and pressure-pain tolerance measurements were taken with the algometer, and recorded.

The subjective measurements were taken using the following questionnaires:


The objective and subjective readings were taken, before the treatments, at the start of the first, second, third and eighth consultations.
3.6.1. ALGOMETER READINGS

The algometer readings were used to assess any change in the patients' pressure-pain threshold and pressure pain tolerance objectively (Appendix 9). Fischer (1986) reported that the algometer could be used to reliably quantify the tenderness of hypersensitive spots. The origin of pain in the tender areas may originate from tendons, ligaments, joint capsules and periosteum (Fischer, A.A. 1987). The algometer used was the force dial manufactured by Wagner Instruments: PO Box 1217, Greenwich CT 06836.

The pressure range of the algometer was 11 kg, which is sufficient to measure both the pressure-pain threshold and pressure-pain tolerance in the patients' areas of tenderness around the metatarsals and MTPs.

Readings were taken as follows:

1) Patients were instructed as to how the algometer worked, and it’s function in the study.

2) The area of maximal tenderness was first located through palpation and the patient’s confirmation. This point was recorded as accurately as possible.

3) The algometer gauge was set to zero.

4) The footplate of the algometer was placed over this point with the shaft exerting pressure in the direction exerted on painful palpation.

5) The gauge was turned away from the patient and the pressure increased at approximately 1 kg/cm².
6) The patients were informed to indicate when they first sensed pain produced by the pressure of the algometer. This reading was recorded as their pressure-pain threshold.

7) The examiner then added further pressure until the patient could no longer take the pain and would indicate vocally to the examiner. This was recorded as the pressure-pain tolerance.

Each time these readings were taken, the point of maximal tenderness was located through palpation and the patient's confirmation.

3.6.2. THE SHORT-FORM MCGILL PAIN QUESTIONNAIRE (SF-MPQ)

The SF-MPQ consists of 15 descriptors (representative words). Descriptors 1-11 represent the sensory dimension of pain experience and descriptors 12-15 represent the affective dimension. Combining the sensory and affective dimensions of pain represents the overall pain score. Each descriptor is ranked on an intensity scale of zero=none, 1=mild, 2=moderate and 3=severe (Appendix 6).

Melzack (1975) looked at the correlation coefficients among the measures, based on data obtained from 297 patients suffering several kinds of pain. The SF-MPQ was found to provide quantitative information for pain, and this information can be treated statistically.
3.6.3. THE NUMERICAL PAIN RATING SCALE 101 (NRS-101)

The NRS-101 consists of asking the patient to rate his or her perceived level of pain intensity on a numerical scale from 0 to 100 (Appendix 7). Zero represents one extreme (no pain), and one hundred represents the other extreme (pain as bad as it could be). Therefore two scores are obtained. The numbers stated by the patient as representing his or her level of pain intensity at its worst and his or her level of pain intensity at its least, are the basic data for the NRS-101 (Jenson, M.P. et al. 1986). Jenson et al. (1986) compared six methods of measuring clinical pain intensity and evaluated them according to the following criteria:

1) Ease of administration of scoring
2) Relative rates of incorrect responding
3) Sensitivity as defined by the statistical power
4) The magnitude of the relationship between each scale, and the linear combination of the pain indices

NRS-101 was found to be the most practical index.

3.6.4. THE FOOT FUNCTION INDEX (FFI)

The FFI was developed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction. The FFI consists of 23 items divided into 3 sub-scales (Appendix 8). The sub-scales provide information on three aspects of function - foot pain (subscale 1), disability (subscale 2) and activity limitation.
Budiman-Mak et al. (1991) examined the FFI for test-retest reliability, internal consistency, and construct and criterion validity. A total of 87 patients with rheumatoid arthritis were used in the study. Strong correlation between the FFI total and sub-scale scores and clinical measures of foot pathology supported the criterion validity of the index. The authors suggested that the index should prove useful for both clinical and research purposes.

(subscale 3) - as they relate to foot pathology. The items, in subscales 1 and 2, were scored from 0 – 10. Zero meaning “no pain” and ten meaning “pain as bad as it could be”. The patient circled the appropriate number between 0 and 10, which they perceived as reflecting their level of pain, for each item. These circled numbers in the subscale were added up, giving a total. The maximum number of items that the patient had indicated was applicable in that subscale then divided this total. Any item that was marked “not applicable” was excluded from the study. Subscale 3 involved a simple “yes or no” answer to each of two questions.

Budiman-Mak et al. (1991) examined the FFI for test-retest reliability, internal consistency, and construct and criterion validity. A total of 87 patients with rheumatoid arthritis were used in the study. Strong correlation between the FFI total and sub-scale scores and clinical measures of foot pathology supported the criterion validity of the index. The authors suggested that the index should prove useful for both clinical and research purposes.

3.7 THE LOCATION OF THE DATA

The primary data was obtained from the McGill, NRS-101 and the FFI, and the algometer readings.

The secondary data was collected from current journals, textbooks, Internet and CD-medline at the Technikon Natal library. If the literature was unavailable at the campus library, inter-library loans were used.
3.8 STATISTICAL ANALYSIS

The level of significance was 5% (\( \alpha \geq 0.05 \)), which applied to all the tests. The observed p-value was compared to \( \alpha/2 \) (i.e. 0.025) because the tests were two-sided.

3.8.1 TREATMENT OF THE SUBJECTIVE DATA

Treatment of the subjective data was as follows:

a. The questionnaires were checked immediately upon completion by the researcher, who ensured that they had all been completed correctly.

b. The scores obtained from the NRS-101 were expressed as percentages. The worst and least pain were recorded separately.

c. The scores from the McGill were recorded as whole numbers (the sum of the value of “ticks” ascribed to each column i.e. 0 = none; 1 = mild; 2 = moderate; 3 = severe), with the highest possible score being 45. All the scores from the questionnaires that the patients from Group A – CMT answered, from the initial consultation, were added up and divided by the sample size (i.e. twenty patients). This gave the mean of that consultation for that group. The same procedure was followed for the other consultations (i.e. second, third and final), and was repeated for the same consultations in Group B – Placebo.

d. The FFI scores were recorded as averages for subscale 1 and subscale 2 separately, for each individual questionnaire. These were recorded as FFI – P (Pain) and FFI – D (Disability) respectively. The FFI-P scores, from all the
questionnaires from the initial consultation in Group A – CMT, were added up and divided by the sample size in that group (twenty patients) to give the mean for that consultation. The same procedure was followed for the second, third and final consultations for FFI-P. This procedure was repeated for FFI-D and again in Group B – Placebo.

e. The data was recorded separately for group A and B.

f. The data was then statistically analysed.

Non-parametric methods were used to analyse categorical variables (Mcgill and NRS-101) and parametric methods were used to analyse continuous variables (FFI).

### 3.8.2 TREATMENT OF THE OBJECTIVE DATA

Treatment of the objective data was as follows:

1) The readings obtained from the algometer for pressure pain threshold and tolerance were jotted on tables in two separate columns.

2) The data was recorded separately for group A and B.

3) The data was then statistically analysed

Parametric methods were used to analyse the algometer readings (continuous variables).
3.8.3 PROCEDURE ONE: Comparison Between Two Unpaired (independent) Samples

1) For Categorical Variables

The Mann-Whitney unpaired U-test was used to compare two independent samples with respect to the categorical variables i.e. those variables that were measured in nominal or ordinal scales and include the FFI. In each test, the null hypothesis states that there is no significant difference between groups A (CMT) and B (Placebo) with respect to the variable in charge, at the $\alpha \geq 0.05$ level of significance. The alternative hypothesis states that there is a significant difference.

2) For Continuous Variables

The two-sample unpaired t-test was used to compare two independent samples with respect to the continuous variables and include the SF-MPQ, the NRS-101 and the algometer readings. In each test, the null hypothesis states that there is no significant difference between groups A (CMT) and B (placebo) with respect to the variable in charge, at the $\alpha \geq 0.05$ level of significance. The alternative hypothesis states that there is a significant difference.

3) Decision Rule

The null hypothesis was rejected at the $\alpha$ level of significance if $p<0.025$ where $p$ was the observed significance level or $p$-value. Otherwise, the null hypothesis is accepted at the same level.
3.8.4 PROCEDURE TWO: Comparison Between Two Related Samples Within Group A

1) For Categorical Variables

For the categorical variables, the Wilcoxon’s signed rank test was used to compare results from related samples. In each test, the null hypothesis states that there is no significant improvement between the two related samples being compared, at the \( \alpha \) level of significance. The alternative hypothesis states that there is a significant improvement.

2) For Continuous Variables

For the continuous variables, the two-sample paired t-test was used to compare the results from the related samples. In each test, the null hypothesis states that there is no significant improvement between the two related samples being compared, at the \( \alpha \) level of significance. The alternative hypothesis states that there is a significant improvement.

3) Decision Rule

The null hypothesis was rejected at the \( \alpha \) level of significance if \( p<\alpha/2 \) where \( p \) was the observed significance level or \( p \)-value. Otherwise, the null hypothesis was accepted at the same level.
3.8.5 PROCEDURE THREE: Comparison Between Related Samples Within Group B

Procedure Two was repeated within group B, with the same decision rule.

3.8.6 PROCEDURE FOUR: Summary Statistics

1) Means and Variances for Categorical Variables

Frequencies and percentages were computed for categorical variables only. Medians were used for the construction of bar charts in the case of categorical variables.

2) Means and Variances for Continuous Variables

Averages and variances were computed for continuous variables only, and were used for power analysis, and means were used for the construction of bar charts. Power analysis was done for continuous variables only.

3.8.7 PROCEDURE FIVE

Visual summaries of the analytical findings were given by the use of bar charts to compare groups A and B with respect to the continuous and categorical variables. Average (mean and median) readings were used to construct bar charts.
3.8.8 PROCEDURE SIX

The powers of each two-sample unpaired t-test were computed using the following UCLA website: http://www.stat.ucla.edu/calculators/powercalc/normal

Each test was two-sided and the variable involved was continuous.

3.8.9 STATISTICAL PACKAGE

The data collected from the first, second, third and final consultations were collated onto spreadsheets. The information obtained from the data entry was statistically analysed using the statistical package, SPSS, for data entry and analysis SPSS Inc. 1999) at the Mathematics Department of the Technikon Natal under the supervision of Mr J. Cloete.
CHAPTER FOUR

THE RESULTS

4.1 INTRODUCTION

This chapter represents the statistical analysis of the data collected, described in Chapter three, in the form of tables and bar graphs. These were accompanied by relevant interpretations. At the initial consultation (1), the second consultation (2), the third consultation (3) and the final consultation (8) the patients were asked to complete three questionnaires; namely the short-form McGill Pain Questionnaire, the Numerical Pain Rating – 101 and the Foot Function Index. At the same consultations, readings were taken of the patients’ sensitivity to pressure with the use of the algometer.

Once these recordings had been rated, they were then collated onto a spreadsheet from which the data was statistically analysed. Both parametric and non-parametric tests were used for the statistical analysis of the data. For the continuous variables, namely the Algometer readings and the FFI, the two-sample unpaired t-test and the two-sample paired t-test were used. In the case of categorical variables, namely the SF-MPQ and the NRS-101, the Mann-Whitney unpaired U test and the Wilcoxon’s Signed Rank Test were used. The null (H0) and alternate hypotheses (H1) were either accepted or rejected based on the statistical criteria for each measurement parameter. In each test, the null hypothesis (H0) states that there is no significant improvement between the two related samples being compared, at the α level of significance (5%).
The alternate hypothesis (H1) states that there is a significant improvement, which is the confidence interval (95%).

In addition, the power of the tests performed on the continuous variables in the study, was used to determine the sensitivity of those tests.

**KEY FOR ABBREVIATIONS**

S.D = Standard Deviation

S.E = Standard Error
4.2. DEMOGRAPHICAL DATA

The demographical data was collected from History (Appendix A) and regional examinations at the initial visits, of both group A (CMT) and group B (Placebo).

Table 1: Demographical data; patient data

<table>
<thead>
<tr>
<th></th>
<th>Group A - CMT</th>
<th>Group B - Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age of patient</strong></td>
<td>Average: 45.7</td>
<td>Average: 53.5</td>
</tr>
<tr>
<td></td>
<td>Youngest: 20</td>
<td>Youngest: 28</td>
</tr>
<tr>
<td></td>
<td>Oldest: 70</td>
<td>Oldest: 78</td>
</tr>
<tr>
<td><strong>Gender Distribution</strong></td>
<td>Female: 13</td>
<td>Female: 13</td>
</tr>
<tr>
<td></td>
<td>Male: 7</td>
<td>Male: 7</td>
</tr>
<tr>
<td><strong>Race Distribution</strong></td>
<td>Black: 0</td>
<td>Black: 0</td>
</tr>
<tr>
<td></td>
<td>Coloured: 0</td>
<td>Coloured: 2</td>
</tr>
<tr>
<td></td>
<td>Indian: 2</td>
<td>Indian: 2</td>
</tr>
<tr>
<td></td>
<td>White: 18</td>
<td>White: 16</td>
</tr>
<tr>
<td></td>
<td><strong>Group a -CMT</strong></td>
<td><strong>Group B – Placebo</strong></td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td><strong>Chronicity</strong></td>
<td>Average: 3.54 years</td>
<td>Average: 3.54 years</td>
</tr>
<tr>
<td></td>
<td>Most: 20 years</td>
<td>Most: 20 years</td>
</tr>
<tr>
<td></td>
<td>Least: 2 days</td>
<td>Least: 5</td>
</tr>
<tr>
<td><strong>Metatarsal heads</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Affected</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2(^{nd}): 6</td>
<td>2(^{nd}): 7</td>
<td></td>
</tr>
<tr>
<td>2(^{nd}), 3(^{rd}): 3</td>
<td>2(^{nd}), 3(^{rd}): 1</td>
<td></td>
</tr>
<tr>
<td>2(^{nd}), 3(^{rd}), 4(^{th}): 7</td>
<td>2(^{nd}), 3(^{rd}), 4(^{th}): 8</td>
<td></td>
</tr>
<tr>
<td>3(^{rd}): 1</td>
<td>3(^{rd}): 0</td>
<td></td>
</tr>
<tr>
<td>4(^{th}): 3</td>
<td>4(^{th}): 2</td>
<td></td>
</tr>
<tr>
<td>2(^{nd}), 3(^{rd}), 4(^{th}), 5(^{th}): 0</td>
<td>2(^{nd}), 3(^{rd}), 4(^{th}), 5(^{th}): 2</td>
<td></td>
</tr>
<tr>
<td><strong>Feet Affected</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right: 6</td>
<td>Right: 4</td>
<td></td>
</tr>
<tr>
<td>Left: 8</td>
<td>Left: 7</td>
<td></td>
</tr>
<tr>
<td>Both: 6</td>
<td>Both: 9</td>
<td></td>
</tr>
</tbody>
</table>
4.3 THE INTER-GROUP COMPARISON FOR CATEGORICAL VARIABLES: NON-PARAMETRIC MANN-WHITNEY UNPAIRED U-TEST

This statistical method was used to compare results from two independent samples with respect to the categorical variable i.e. the SF-MPQ and NRS-101.

4.3.1 SUBJECTIVE DATA

Tables 3: Statistical results comparing the response to treatment of Group A – CMT and Group B – Placebo before each consultation, in terms of subjective measurements

Table 3.1: The SF-MPQ

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial A with Initial B</td>
<td>.001</td>
</tr>
<tr>
<td>Second A with Second B</td>
<td>.011</td>
</tr>
<tr>
<td>Third A with Third B</td>
<td>.008</td>
</tr>
<tr>
<td>Final A with Final B</td>
<td>.018</td>
</tr>
</tbody>
</table>

There was a statistically significant difference between Group A – CMT and Group B – Placebo at the initial (prior to treatment), first, second and final visits (in favour of Group A – CMT); with the initial visit showing the greatest difference. This leads to the rejection of the null hypothesis and the acceptance of the alternative hypothesis,
indicating that the two groups differed in terms of their perception of pain and disability throughout the study.

Table 3.2: The NRS-101: worst pain

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial A with Initial B</td>
<td>.007</td>
</tr>
<tr>
<td>Second A with Second B</td>
<td>.018</td>
</tr>
<tr>
<td>Third A with Third B</td>
<td>.006</td>
</tr>
<tr>
<td>Final A with Final B</td>
<td>.035</td>
</tr>
</tbody>
</table>

There was a statistically significant difference between Group A – CMT and Group B – Placebo on the initial, second and third visits (in favour of Group A – CMT), leading to the rejection of the null hypothesis and the acceptance of the alternative hypothesis during these visits. This indicates that the two groups differed in terms of worst pain at the beginning of the study. Clinically, Group A – CMT was better than Group B – Placebo. There was no statistically significant difference between the two groups on the final visit, leading to the acceptance of the null hypothesis, indicating that the two groups were similar in terms of worst pain at the final visit.
Table 3.3: The NRS – 101: least pain

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial A with Initial B</td>
<td>.119</td>
</tr>
<tr>
<td>Second A with Second B</td>
<td>.007</td>
</tr>
<tr>
<td>Third A with Third B</td>
<td>.010</td>
</tr>
<tr>
<td>Final A with Final B</td>
<td>.006</td>
</tr>
</tbody>
</table>

There was no statistically significant difference between Group A – CMT and Group B – Placebo at the initial visit, indicating that the two groups were similar in terms of least pain at the beginning of the study.

There was a statistically significant difference between the two groups at the second, third and final visits (in favour of Group A – CMT), leading to the acceptance of the null hypothesis, indicating that the two groups differed in terms of least pain through the treatment.
4.4 THE INTER-GROUP COMPARISON FOR CONTINUOUS VARIABLES:  
PARAMETRIC TWO-SAMPLE UNPAIRED T-TEST

This statistical method was used to compare results from two independent samples with respect to the continuous variables i.e. FFI: subscale 1 (FFI-P) and subscale 2 (FFI-D), and the Algometer readings: pain threshold and pain tolerance.

4.4.1 SUBJECTIVE DATA

Table 4: Statistical results comparing Group A – CMT and Group B – Placebo in terms of FFI measurements for the initial consultation

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th></th>
<th>Group B – Placebo</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial Consultation</td>
<td></td>
<td>Initial Consultation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
<td>S.E.</td>
<td>P-value</td>
</tr>
<tr>
<td>FFI – P</td>
<td>4.4900</td>
<td>1.9352</td>
<td>.4327</td>
<td>.047</td>
</tr>
<tr>
<td>FFI – D</td>
<td>3.1356</td>
<td>2.4523</td>
<td>.5483</td>
<td>.557</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted in both instances, as there was no statistically significant difference between the subjective data (FFI-P and FFI-D), of Group A and Group B at the initial consultation. This indicated that the two groups were similar in terms of perception pain and disability at the initial consultation.
Table 5: Statistical results comparing Group A – CMT and Group B – Placebo in terms of FFI measurements for the second consultation

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th></th>
<th>Group B – Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Second Consultation</td>
<td>Second Consultation</td>
<td></td>
</tr>
<tr>
<td>MEAN</td>
<td>S.D.</td>
<td>S.E.</td>
<td>P-value</td>
</tr>
<tr>
<td>FFI-P</td>
<td>3.5500</td>
<td>1.9444</td>
<td>.4348</td>
</tr>
<tr>
<td>FFI-D</td>
<td>2.4214</td>
<td>2.2308</td>
<td>.4988</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for FFI-P, as there was a statistically significant difference between the subjective data (FFI-P), of Group A and Group B at the second consultation. In this case the alternative hypothesis was accepted, which indicated that the two groups differed in terms of their perception pain at the second visit, with Group A – CMT experiencing less pain. Group A’s mean was significantly less than Group B’s, meaning they were experiencing less pain.

The null hypothesis was accepted for FFI-D, as there was no statistically significant difference between the groups. This indicated that the two groups were similar in terms of perception of disability at the second visit.
Table 6: Statistical results comparing Group A – CMT and Group B – Placebo in terms of FFI measurements for the third consultation

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th>Group B – Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Third Consultation</td>
<td>Third Consultation</td>
</tr>
<tr>
<td><strong>MEAN</strong></td>
<td>S.D.</td>
<td>S.E.</td>
</tr>
<tr>
<td>FFI – P</td>
<td>2.5300</td>
<td>2.1465</td>
</tr>
<tr>
<td>FFI – D</td>
<td>1.6421</td>
<td>2.0115</td>
</tr>
<tr>
<td></td>
<td>4.1600</td>
<td>1.8406</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for FFI-P, as there was a statistically significant difference between the subjective data (FFI-P), of Group A and Group B at the third consultation (in favour of Group A – CMT). In this case the alternative hypothesis was accepted, which indicated that the two groups differed in terms of pain, at the third visit, with Group A – CMT experiencing less pain.

The null hypothesis was accepted for FFI-D, as there was no statistically significant difference between the groups, although the difference tended towards significance. This indicated that the two groups experienced no difference in their of perception of disability at the second visit.
Table 7: Statistical results comparing Group A – CMT and Group B – Placebo in terms of FFI measurements for the final consultation

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th>Group B – Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final Consultation</td>
<td>Final Consultation</td>
</tr>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI – P</td>
<td>1.3600</td>
<td>1.4919</td>
</tr>
<tr>
<td>FFI – D</td>
<td>0.7428</td>
<td>1.1386</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected in both instances, as there was a statistically significant difference between the subjective data (FFI-P and FFI-D), of Group A and Group B at the final consultation (in favour of Group A – CMT). This indicates that the two groups differed in terms of pain and disability at the end of the study. The mean values of Group A were significantly less than those of Group B, meaning Group A – CMT experienced less pain and disability at the completion of the study.
4.4.2 OBJECTIVE DATA

Table 8: Statistical results comparing Group A – CMT and Group B – Placebo in terms of the objective measurements (Algometer readings) for the initial consultations

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th>Group B – Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial Consultation</td>
<td>Initial Consultation</td>
</tr>
<tr>
<td><strong>MEAN</strong></td>
<td><strong>S.D.</strong></td>
<td><strong>S.E.</strong></td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.5750</td>
<td>.9829</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.2500</td>
<td>1.5060</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for the Algometer readings, as there was no statistically significant difference between the objective data (Pain Threshold and Pain Tolerance), of Group A and Group B at the initial consultation. This indicated that the two groups were similar in terms of objective findings at the initial consultation.
Table 9: Statistical results comparing Group A – CMT and Group B – Placebo in terms of the objective measurements (Algometer readings) for the second consultations

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th></th>
<th>Group B – Placebo</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Second Consultation</td>
<td></td>
<td>Second Consultation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
<td>S.E.</td>
<td>P-value</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.9550</td>
<td>1.2659</td>
<td>.2831</td>
<td>.918</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.5900</td>
<td>1.6121</td>
<td>.3605</td>
<td>.385</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted in both instances, as there was no statistically significant difference between the objective data (Pain Threshold and Pain Tolerance), of Group A and Group B at the second consultation. This indicated that the two groups were similar in terms of objective findings at the second consultation.
Table 10: Statistical results comparing Group A – CMT and Group B – Placebo in terms of the objective measurements (Algometer readings) for the third consultations

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT Third Consultation</th>
<th>Group B – Placebo Third Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>3.1850</td>
<td>1.4147</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.8400</td>
<td>1.8630</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted in both instances, as there was no statistically significant difference between the objective data (Pain Threshold and Pain Tolerance), of Group A and Group B at the third consultation. This indicated that the two groups were similar in terms of objective findings at the third consultation.
Table 11: Statistical results comparing Group A – CMT and Group B – Placebo in terms of the objective measurements (Algometer readings) for the final consultations

<table>
<thead>
<tr>
<th></th>
<th>Group A – CMT</th>
<th></th>
<th></th>
<th>Group B – Placebo</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final Consultation</td>
<td>Final Consultation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
<td>S.E.</td>
<td>P-value</td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>3.7650</td>
<td>1.4001</td>
<td>.3131</td>
<td>.288</td>
<td>3.2905</td>
<td>1.3860</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>6.1450</td>
<td>2.1135</td>
<td>.4726</td>
<td>.020</td>
<td>4.6850</td>
<td>1.6791</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold, as there was no statistically significant difference between Group A and Group B at the final consultation. This indicated that the two groups were similar in terms of objective findings at the final consultation.

The null hypothesis was rejected for Pain Tolerance, as there was a statistically significant difference between the two groups. The alternative hypothesis was accepted in this case, indicating that there was a significant difference between the objective measurements of Groups A and B, at the final consultation. Group A – CMT’s mean was significantly higher than Group B – Placebo’s, which indicated their pain tolerance was significantly higher.
4.5 INTRA-GROUP COMPARISON FOR CATEGORICAL VARIABLES:

NON-PARAMETRIC WILCOXON’S SIGNED RANK TEST

This statistical method was used to compare results from two related samples with respect to categorical variables i.e. the McGill and NRS-101.

4.5.1 SUBJECTIVE DATA

Tables 12: Statistical results comparing initial, second, third and final consultations in Group A – CMT in terms of subjective measurements

Table 12.1: The SF-MPQ

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial A with Second A</td>
<td>.003</td>
</tr>
<tr>
<td>Second A with Third A</td>
<td>.004</td>
</tr>
<tr>
<td>Third A with Final A</td>
<td>.001</td>
</tr>
<tr>
<td>Initial A with Final A</td>
<td>.000</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparison between all the consultations. This indicated a statistically significant difference, indicating a subjective improvement between these consultations as a result of CMT.
Table 12.2: NRS-101: worst pain

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial A with Second A</td>
<td>.011</td>
</tr>
<tr>
<td>Second A with Third A</td>
<td>.019</td>
</tr>
<tr>
<td>Third A with Final A</td>
<td>.001</td>
</tr>
<tr>
<td>Initial A with Final A</td>
<td>.000</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparison between all the consultations. This indicated a statistically significant difference, indicating a subjective improvement between these consultations as a result of CMT.
The null hypothesis was accepted for the comparison between the initial and second consultations, the second and third consultations, and the third and final consultations. This indicated no statistically significant difference between these consultations. There was however, a statistically significant difference between the initial and final consultations, indicating a subjective improvement overall as a result of CMT.

Table 12.3: NRS – 101: least pain

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial A with Second A</td>
<td>.419</td>
</tr>
<tr>
<td>Second A with Third A</td>
<td>.256</td>
</tr>
<tr>
<td>Third A with Final A</td>
<td>.041</td>
</tr>
<tr>
<td>Initial A with Final A</td>
<td>.001</td>
</tr>
</tbody>
</table>
Tables 13: Statistical results comparing initial, second, third and final consultations in Group B – Placebo in terms of subjective measurements

Table 13.1: The SF-MPQ

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial B with Second B</td>
<td>.087</td>
</tr>
<tr>
<td>Second B with Third B</td>
<td>.088</td>
</tr>
<tr>
<td>Third B with Final B</td>
<td>.396</td>
</tr>
<tr>
<td>Initial B with Final B</td>
<td>.004</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for the comparison between the initial and second consultations, the second and third consultations, and the third and final consultations. This indicated no statistically significant difference between these consultations.

There was however, a statistically significant difference between the initial and final consultations, indicating a subjective improvement overall as a result of placebo treatment, or possibly due to the natural history of the disease.
Table 13.2: NRS – 101: worst pain

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial B with Second B</td>
<td>.152</td>
</tr>
<tr>
<td>Second B with Third B</td>
<td>.190</td>
</tr>
<tr>
<td>Third B with Final B</td>
<td>.010</td>
</tr>
<tr>
<td>Initial B with Final B</td>
<td>.000</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for the comparison between the initial and second consultations, and the second and third consultations. This indicated no statistically significant difference between these consultations.

There was however, a statistically significant difference between the third and final consultations, and the initial and final consultations, indicating a subjective improvement overall as a result of placebo treatment.
Table 13.3: NRS – 101: least pain

<table>
<thead>
<tr>
<th>CONSULTATIONS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial B with Second B</td>
<td>.234</td>
</tr>
<tr>
<td>Second B with Third B</td>
<td>.324</td>
</tr>
<tr>
<td>Third B with Final B</td>
<td>.268</td>
</tr>
<tr>
<td>Initial B with Final B</td>
<td>.695</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for the comparison between all the consultations. This indicated no statistically significant difference, indicating no subjective improvement between these consultations as a result of placebo treatment.
4.6 INTRA-GROUP COMPARISON FOR CONTINUOUS VARIABLES: THE PARAMETRIC TWO-SAMPLE PAIRED T-TEST

This statistical method was used to compare results from two related samples within a group with respect to continuous variables i.e. the FFI: subscales A(FFI-P) and B (FFI-D), and Algometer readings: pain threshold and pain tolerance..

4.6.1 SUBJECTIVE DATA

Table 14: Statistical results comparing the initial consultation and the second consultation in Group A – CMT in terms of subjective measurements

<table>
<thead>
<tr>
<th>GROUP A – CMT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Initial Consultation</strong></td>
</tr>
<tr>
<td>MEAN</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>FFI – P</td>
</tr>
<tr>
<td>FFI – D</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparison between the initial and second consultations for FFI-p, which indicated subjective pain improvement between these consultations, as a result of CMT.
The null hypothesis is however accepted for FFI-D (although it tends strongly towards the alternative hypothesis), indicating no subjective improvement in function between the same consultations, as a result of CMT.

Table 15: Statistical results comparing the second consultation and the third consultation in Group A – CMT in terms of subjective measurements

<table>
<thead>
<tr>
<th>Second Consultation</th>
<th>Third Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI-P</td>
<td>3.5500</td>
</tr>
<tr>
<td>FFI-D</td>
<td>2.4214</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparisons between the second and third consultations for FFI-P and FFI-D, which indicated subjective improvement of pain and function between these consultations, as a result of CMT.
Table 16: Statistical results comparing the third consultation and the final consultation in Group A - CMT in terms of subjective measurements

**GROUP A – CMT**

<table>
<thead>
<tr>
<th>Third Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEAN</strong></td>
<td><strong>S.D.</strong></td>
</tr>
<tr>
<td>FFI – P</td>
<td>2.5300</td>
</tr>
<tr>
<td>FFI – D</td>
<td>1.6421</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparisons between the third and final consultations for FFI-P and FFI-D, which indicated subjective improvement of pain and function between these consultations, as a result of CMT.
Table 17: Statistical results comparing the first consultation and the final consultation in Group A - CMT in terms of subjective measurements

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI - P</td>
<td>4.4900</td>
<td>1.9352</td>
</tr>
<tr>
<td>FFI - D</td>
<td>3.1356</td>
<td>2.4523</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparisons between the initial and final consultations for FFI-P and FFI-D, which indicated subjective improvement of pain and function from the treatment overall, as a result of CMT.
Table 18: Statistical results comparing the first consultation and the second consultation in Group B - Placebo in terms of subjective measurements.

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th>Second Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI - P</td>
<td>5.6600</td>
<td>1.6506</td>
</tr>
<tr>
<td>FFI - D</td>
<td>3.6287</td>
<td>2.8052</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for FFI-P and FFI-D, indicating no subjective improvement in function between the first and second consultations, as a result of placebo treatment.
Table 19: Statistical results comparing the second consultation and the third consultation in Group B - Placebo in terms of subjective measurements

<table>
<thead>
<tr>
<th></th>
<th>Second Consultation</th>
<th>Third Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI – P</td>
<td>5.1400</td>
<td>1.7581</td>
</tr>
<tr>
<td>FFI – D</td>
<td>3.6219</td>
<td>2.7205</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparison between the second and third consultations for FFI-P, which indicated subjective pain improvement between these consultations, as a result of placebo treatment.

The null hypothesis is however accepted for FFI-D, indicating no subjective improvement in function between the same consultations, as a result of placebo treatment.
Table 20: Statistical results comparing the third consultation and the final consultation in Group B - Placebo in terms of subjective measurements.

<table>
<thead>
<tr>
<th></th>
<th>Third Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI - P</td>
<td>4.1600</td>
<td>1.8406</td>
</tr>
<tr>
<td>FFI - D</td>
<td>3.2644</td>
<td>2.4807</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for FFI-P and FFI-D, indicating no subjective improvement in function between the third and final consultations, as a result of placebo treatment.
Table 21: Statistical results comparing the first consultation and the final consultation in Group B - Placebo in terms of subjective measurements

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>FFI - P</td>
<td>5.6600</td>
<td>1.6506</td>
</tr>
<tr>
<td>FFI - D</td>
<td>3.6287</td>
<td>2.8052</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for the comparisons between the initial and final consultations for FFI-P and FFI-D, which indicated subjective improvement of pain and function from the treatment overall, as a result of placebo treatment.
4.6.2 OBJECTIVE DATA

Table 22: Statistical results comparing the initial consultation and the second consultation in Group A - CMT in terms of objective measurements

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th></th>
<th></th>
<th>Second Consultation</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
<td>S.E</td>
<td>P-value</td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.5700</td>
<td>.9289</td>
<td>.2198</td>
<td>.050</td>
<td>2.9550</td>
<td>1.2659</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.2500</td>
<td>1.5060</td>
<td>.3367</td>
<td>.176</td>
<td>4.5900</td>
<td>1.6121</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold and Pain Tolerance, indicating no objective improvement between the first and second consultations, as a result of CMT.
Table 23: **Statistical results comparing the second consultation and the third consultation in Group A – CMT in terms of objective measurements**

<table>
<thead>
<tr>
<th>GROUP A – CMT</th>
<th>Second Consultation</th>
<th>Third Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.9550</td>
<td>1.2659</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.5900</td>
<td>1.6121</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold and Pain Tolerance, indicating no objective improvement between the second and third consultations, as a result of CMT.
Table 24: Statistical results comparing the third consultation and the final consultation in Group A - CMT in terms of objective measurements.

<table>
<thead>
<tr>
<th></th>
<th>Third Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>3.1850</td>
<td>1.4147</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.8400</td>
<td>1.8630</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for Pain Threshold and Pain Tolerance, indicating an objective improvement between the third and final consultations, as a result of CMT.
Table 25: Statistical results comparing the first consultation and the final consultation in Group A – CMT in terms of objective measurements

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th></th>
<th>Final Consultation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
<td>S.E.</td>
<td>P-value</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.5750</td>
<td>.9829</td>
<td>.2198</td>
<td>.000</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.2500</td>
<td>1.5060</td>
<td>.3367</td>
<td>.000</td>
</tr>
</tbody>
</table>

The null hypothesis was rejected for Pain Threshold and Pain Tolerance, indicating an objective improvement between the third and final consultations, as a result of CMT.
Table 26: Statistical results comparing the first consultation and the second consultation in Group B - Placebo in terms of objective measurements

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th>Second Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.9750</td>
<td>1.2426</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.4100</td>
<td>1.6565</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold and Pain Tolerance, indicating no objective improvement between the first and second consultations, as a result of placebo treatment.
Table 27: Statistical results comparing the second consultation and the third consultation in Group B - Placebo in terms of objective measurements

<table>
<thead>
<tr>
<th></th>
<th>Second Consultation</th>
<th>Third Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.9950</td>
<td>1.1605</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.1700</td>
<td>1.4027</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold and Pain Tolerance, indicating no objective improvement between the second and third consultations, as a result of placebo treatment.
Table 28: Statistical results comparing the third consultation and the final consultation in Group B - Placebo in terms of objective measurements.

GROUP B - PLACEBO

<table>
<thead>
<tr>
<th></th>
<th>Third Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>3.1150</td>
<td>1.4310</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.6750</td>
<td>1.8344</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold and Pain Tolerance, indicating no objective improvement between the third and final consultations, as a result of placebo treatment.
Table 29: Statistical results comparing the first consultation and the final consultation in Group B - Placebo in terms of objective measurements

GROUP B – PLACEBO

<table>
<thead>
<tr>
<th></th>
<th>First Consultation</th>
<th>Final Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>S.D.</td>
</tr>
<tr>
<td>Pain Threshold</td>
<td>2.9750</td>
<td>1.2426</td>
</tr>
<tr>
<td>Pain Tolerance</td>
<td>4.4100</td>
<td>1.6565</td>
</tr>
</tbody>
</table>

The null hypothesis was accepted for Pain Threshold and Pain Tolerance, indicating no objective improvement between the first and final consultations, as a result of placebo treatment.
4.7 DATA SCORES

Figure 1: Graphical comparison of McGill median scores for Groups A and B

SF-MPQ

Medians

<table>
<thead>
<tr>
<th>Consultations</th>
<th>Initial</th>
<th>Second</th>
<th>Third</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Group B</td>
<td>14</td>
<td>10</td>
<td>8</td>
<td>6</td>
</tr>
</tbody>
</table>
Figures 2: Graphical comparison of NRS-101 median scores (as percentages) for Groups A and B

Figure 2.1:

NRS-101: Worst Pain

![Graph showing median scores for worst pain](image)

Figure 2.2:

NRS-101: Least Pain

![Graph showing median scores for least pain](image)
Figure 3.1: Graphical comparison of FFI-P (mean scores as percentages) for Groups A and B:

![Diagram of FFI-P](image)

Figure 3.2: Graphical comparison of FFI-D (mean scores as percentages) for Groups A and B:

![Diagram of FFI-D](image)
Figures 4: Graphical comparison of Algometer readings (mean scores as percentages) for Groups A and B:

Figure 4.1:

Pain Threshold

![Pain Threshold Chart]

Figure 4.2:

Pain Tolerance

![Pain Tolerance Chart]
The power of a statistical test is a measure of how sensitive the test is. The power of a test depends on the size of the sample, the accuracy of the measurements involved in the study and the level of significance of the study, $\alpha$. In this study, the sample size was small, at twenty patients per group, and the measurements were subject to human error; both of these weaken the power of the statistical tests.

The smaller the power of a test, the larger becomes the likelihood of a Type II error (accepting a false null hypothesis). In this case, FFI-A (second, third and final consultations), FFI-B (final consultation) and pain tolerance (final consultation) show
high power values. This indicates a decreased likelihood of Type II errors in the statistical analysis of these cases.
CHAPTER FIVE

DISCUSSION OF THE RESULTS

5.1 INTRODUCTION

The results obtained from the subjective and objective data are discussed in this chapter. The interpretation of the results is necessary to ascertain whether or not the premise that CMT of the foot and ankle joints is effective in the treatment of primary metatarsalgia, is substantiated.

5.2 INTERPRETATION OF THE DEMOGRAPHICAL DATA

The age range of patients participating in the study was 20 – 78 years, with the average age being 49.5 years (Table 1). This is supported by the literature (Matheson et al. 1989, Subotnik, S.I. 1989: 563, and Levy, L.A. and Hetherington, V.J. 1990: 563), which suggests that metatarsalgia is more common amongst the older population.

The gender distribution in the study is fourteen males to twenty-six females (Table 1), showing a significant preponderance of females to males. In the author’s opinion, this is most likely due to the shoes that females wear: high heels, thin soles and narrow toe box. Jahss (1982: 1240) also suggests that high-heeled shoes are implicated in causing metatarsalgia.
This study showed that of the participating patients, two were Coloured, four were Indian, and thirty-four were White. No Blacks partook of the study. This is an unrealistic sample of the distribution of metatarsalgia sufferers amongst various racial populations of South Africa. This probably was a result of advertising in the greater Durban and Highway areas, which are frequented mostly by Whites and Indians. Because of this, the racial demographics of metatarsalgia are not truly reflected in this study and therefore hold little significance.

The data gathered from the patient history and regional examinations, at the commencement of the study, showed that the average length of time that the patients had the condition for was 5.95 years (Table 2). This is an indication of the chronicity of the condition.

The data also indicated that the left foot was more often affected (fifteen patients) than the right foot (ten patients); with both feet affected (fifteen patients) being fairly prevalent. However, these differences are not significant enough with this sample size.

The metatarsals most commonly affected were the second metatarsal (thirteen patients), and the second, third and fourth metatarsals (fifteen patients). Five patients experienced the fourth metatarsal as the problem area. There appeared to be little correlation between the metatarsals involved, and a particular activity, e.g. sporting activities.
5.3 INTER-GROUP TREATMENT COMPARISON

The comparison of the subjective and objective data of both groups from the initial consultation revealed any differences between the two groups in terms of their original signs and symptoms. The comparison of the results at the second and third consultations confirmed which treatment protocol had relatively greater benefit early in the treatment program. The comparison of the results from the final treatment confirmed which treatment protocol was relatively more effective in the treatment of primary metatarsalgia.

5.3.1. SUBJECTIVE DATA

a. The Short-Form McGill Pain Questionnaire

Comparison of the first consultation of both groups showed a statistically significant difference \( p = 0.001 \), indicating that the groups differed with respect to pain perception (Table 3.1). Group A – CMT had a less severe pain response than Group B – Placebo, which is clearly illustrated in Figure 1.

Comparison of the second consultation of both groups and third consultation of both groups showed statistically significant differences \( p = 0.011 \) and \( p = 0.008 \), respectively) between the two groups (Table 3.1). This indicated a difference in the pain perception between the two groups, in favour of Group A – CMT (Figure 1).

The final consultation comparisons of both groups showed statistically significant differences \( p = 0.001 \) between the two groups (Table 3.1). This indicated a
difference in the pain perception between the two groups (in favour of Group A – CMT), with Group A – CMT responding better than Group B – Placebo.

Summary

As there was a statistically significant difference between the two groups at the initial consultation, this indicated that the two groups exhibited differences between their original pain perceptions. A statistically significant difference at the final consultation indicated that the two groups remained divided on their response to pain perception, although clinically both improved. Group A – CMT showed greater improvement.

b. The Numerical Pain Rating Scale – 101

Comparison of the first consultation of the two groups revealed that there was a statistically significant difference in terms of worst pain ($p = 0.007$) but not in terms of least pain ($p = 0.119$); indicating that the two groups differed with regards to their original perception of worst pain, but they were similar in their original perception of least pain (Tables 3.2 and 3.3, respectively). In both cases, Group B – Placebo perceived their pain as more severe than did Group A – CMT (Figures 2.1 and 2.2, respectively).

The analysis of the readings of the second consultation revealed a statistically significant difference with both the worst and least pain ($p = 0.018$ and $p = 0.007$, respectively), as did the analysis of the readings of the third consultation ($p = 0.006$ and $p = 0.010$; worst and least pain respectively). Therefore the two groups differed
with regards to their worst and least pain at these consultations, with Group A – CMT showing a lower median score throughout the treatment period.

At the final consultation, the null hypothesis is accepted for the worst pain \( (p = 0.035) \), indicating that the two groups were similar with regards to their perception of worst pain at the end of the treatment. The null hypothesis is however rejected for the least pain \( (p = 0.006) \), indicating that the two groups differed with regards to their perception of least pain at the end of the treatment.

**Summary**

Group B – Placebo responded favourably in terms of Worst Pain, but not as much in terms of Least Pain.

Group A – CMT responded well to the treatment protocol, in terms of Least Pain, with the median of the final treatment being very low (0%). In terms of Worst Pain, the median was also low (20%).

c. **The Foot Function Index**

The inter-group comparison of the initial consultation showed no significant difference for FFI-P or FFI-D \( (p = 0.047 \) and \( p = 0.557 \), respectively), indicating that both groups were similar in terms of pain and function at the commencement of the study (Table 4).
A statistically significant difference was noted for FFI-P ($p = 0.010$), but not for FFI-D ($p = 0.135$), at the second consultation (Table 5).

The same applied to the third consultation with FFI-P ($p = 0.014$) and FFI-D ($p = 0.029$), although in this case, FFI-D tends towards a significant difference. In both cases, the means are less for Group A – CMT (Tables 6).

The final consultation showed statistically significant differences for both FFI-P and FFI-D ($p = 0.001$ and $p = 0.010$, respectively), indicating that both groups differed in terms of pain and function at the completion of the study (Table 7).

**Summary**

Figures 3.1 and 3.2 illustrate the differences between the two groups with respect to FFI-P and FFI-D throughout the study, with the mean of FFI-P being consistently lower than the mean of FFI-D. However, Group A – CMT responded more rapidly to the treatment in terms of pain (FFI-P), than did Group B – Placebo.

It was evident that Group A – CMT responded better to their treatment protocol subjectively than Group B – Placebo, at the completion of the study, in terms of pain and disability.
5.3.2 OBJECTIVE DATA

a. The Algometer Readings

The comparison of the initial Algometer readings presented no statistically significant difference ($p = 0.266$ and $p = 0.751$, for Pain Threshold and Pain Tolerance respectively) between the two groups, indicating that pain sensitivity to pressure was similar at the beginning of the study (Table 8).

The comparison of the data presented no statistically significant difference at the second ($p = 0.918$ and $p = 0.385$, for Pain Threshold and Pain Tolerance respectively) (Table 9) and third ($p = 0.288$ and $p = 0.779$, for Pain Threshold and Pain Tolerance respectively) (Table 10) consultations between the two groups, indicating that pain sensitivity to pressure was similar at these consultations. This indicated that neither treatment protocol was more effective than the other, early on in the study.

The final consultation revealed that Group A - CMT responded better in terms of Pain Tolerance than Group B - Placebo, with a statistically significant difference of $p = 0.020$. However, there was no statistically significant difference in terms of Pain Threshold ($p = 0.288$) (Table 11) at the completion of the study, indicating that neither treatment protocol was superior to the other in terms in reducing Pain Threshold.

Figure 4.1 illustrates the improvement of Group A - CMT compared to Group B - Placebo, in terms of pain threshold; and Figure 4.2, in terms of pain tolerance.
Summary

There was no statistically significant difference between the two groups in terms of Pain Threshold, throughout the study, indicating that no one treatment protocol was superior to the other.

In terms of Pain Tolerance, the only statistically significant difference between the two groups was at the final consultation. This evidence suggests that Group A – CMT’s treatment protocol was more effective in the treatment of primary metatarsalgia.

5.4 INTRA-GROUP TREATMENT COMPARISON

The statistical analysis of the subjective and objective intra-group treatment between the initial to second consultation and the second to third consultation represents the initial relative effectiveness of the treatment protocol.

The comparison of the third to final consultation, and the initial to final consultation represents the relative effectiveness of the treatment protocol as a whole.

This process was done with data of both treatment groups.
5.4.1 SUBJECTIVE DATA

a. The short-form McGill Pain Questionnaire

The analysis of the mean values for the initial to second consultation period depicted a statistically significant improvement in Group A – CMT ($p = 0.003$), but not in Group B – Placebo ($p = 0.087$). The same applied to the second to third consultations, with Group A – CMT and Group B - Placebo having P- values of $p = 0.004$ and $p = 0.088$, respectively. (Tables 12.1 and 13.1)

The third to final consultations showed statistically significant differences for Group A – CMT, but not for Group B – Placebo ($p = 0.001$ and $p = 0.396$, respectively). The comparison between the first to final consultations showed statistically significant differences for both groups: Group A – CMT ($p = 0.000$) and Group B – Placebo ($p = 0.004$). (Tables 12.1 and 13.1). This indicated a decrease of pain perception in both groups over the treatment period.

Summary

The SF-MPQ provides information regarding the sensory, affective and overall intensity of the patients’ pain.

Group A – CMT showed statistically significant improvement from one visit to the next. However, Group B – Placebo showed only significant improvement from the first to the last consultations, but no statistically significant improvement early on in the treatment program. Therefore, although both groups improved overall, only Group
A – CMT improved significantly in terms of patient perception early in the treatment program.

b. The Numerical Pain Rating Scale – 101

Comparison between the initial and second, and second and third consultations for the NRS-101: worst pain showed statistically significant differences for Group A – CMT ($p = 0.011$ and $p = 0.019$, respectively), but not in Group B – Placebo ($p = 0.152$ and $p = 0.190$, respectively). (Table 12.2 and 13.2)

Statistically significant differences were noted for both Group A – CMT and Group B – Placebo, at the comparison between the third and final treatments, with the p-values being $p = 0.001$ and $p = 0.010$, respectively.

Comparisons of the first and final treatments showed p-values of $p = 0.000$ and $p = 0.000$, for Group A – CMT and Group B - Placebo respectively.

In terms of NRS-101: least pain, there was no statistically significant difference for the comparison between consultations in Group B – Placebo, with the p-values being as follows: $p = 0.234$, $p = 0.324$, $p = 0.268$ and $p = 0.695$ (Table 12.3 and 13.3). In Group A – CMT, there was no significant difference in the comparison between the first and second, second and third, and third and final consultations ($p = 0.419$, $p = 0.256$ and $p = 0.041$, respectively). There was however a significant difference
between the response in the first and final consultations \((p = 0.001)\), indicating an overall improvement in the pain perception of the experimental group.

**Summary**

The NRS-101 is a questionnaire that monitors the levels of pain perception experienced by patients. Both groups in the initial to final consultation period showed a statistically significant difference (in terms of Worst Pain), indicating a decrease in pain perception. However, only Group A – CMT showed a statistically significant difference at the earlier visits, i.e. first, second and third visits. In other words, they responded more rapidly to their treatment protocol in terms of their Worst Pain perception.

Neither group responded significantly, in terms of their Least Pain, during the first three consultations and from the third to final consultation, but Group A – CMT responded significantly from the first to final consultation. This indicates that the treatment protocol for Group A was more effective in reducing the patients’ perception of Least Pain.

c. The Foot Function Index

The comparison of between all the visits (i.e. first and second, second and third, third and final, and first and final) for the FFI-P of Group A – CMT showed statistically significant differences: \(p = 0.014, p = 0.020, p = 0.000\) and \(p = 0.000\), respectively (Tables 14 to 17).
The same applied for FFI-D in Group A – CMT, where all showed statistically significant differences, except for the comparison between the first and second visit \((p = 0.025)\). The \(p\)-values for the other visits were \(p = 0.002\), \(p = 0.003\) and \(p = 0.000\), respectively (Tables 14 to 17).

Group B – Placebo showed statistically significant differences, for FFI-P, only in the comparison between the second and third \((p = 0.005)\), and the first and final \((p = 0.002)\) consultations (Tables 18 to 21). There was no significant difference in the comparison between the first and second \((p = 0.127)\), and third and final \((p = 0.228)\) consultations.

With respect to Group B – Placebo’s response in the FFI-D, there was no statistically significant difference in the comparison between the first and second \((p = 0.987)\), second and third \((p = 0.359)\), and third and final \((p = 0.151)\) consultations. There was however a difference between the first and final consultations \((p = 0.013)\).

Summary

The FFI-P is a measure of the patients’ perception of pain, and the FFI-D is a measure of the patients’ perception of disability in connection with foot problems, and the impact on their daily lives. Both groups showed statistically significant differences with respect to FFI-P and FFI-D, in the comparison between the first and final visits. This indicated that both groups improved overall in terms their perception of pain and disability. However, only Group A – CMT improved significantly early in the treatment program, i.e. between visits one, two and three, for both FFI-P and FFI-D.
This indicates that the treatment protocol for Group A - CMT was effective in reducing the patients' perception of pain and disability, more rapidly than placebo.

5.4.2 OBJECTIVE DATA

a. The Algometer Readings

The Algometer readings for Group B - Placebo, both Pain Threshold and Pain Tolerance, showed no statistically significant difference in the comparison between the following consultations: first and second ($p = 0.887$ and $p = 0.175$, for Pain Threshold and Pain Tolerance respectively), second and third ($p = 0.536$ and $p = 0.086$, for Pain Threshold and Pain Tolerance respectively), third and final ($p = 0.473$ and $p = 0.975$, for Pain Threshold and Pain Tolerance respectively), and first and final ($p = 0.355$ and $p = 0.171$, for Pain Threshold and Pain Tolerance respectively) (Tables 25 to 28).

In Group A - CMT, there were no statistically significant differences between the first and second ($p = 0.050$ and $p = 0.176$, for Pain Threshold and Pain Tolerance respectively), and second and third ($p = 0.235$ and $p = 0.252$, for Pain Threshold and Pain Tolerance respectively) consultations (Tables 22 to 24). There were, however, statistically significant differences between the third and final ($p = 0.023$ and $p = 0.001$, for Pain Threshold and Pain Tolerance respectively), and first and final ($p = 0.000$ and $p = 0.000$, for Pain Threshold and Pain Tolerance respectively) consultations.
Summary

The Algometer measures the patients' pressure-pain threshold and pressure-pain tolerance objectively. There was no statistically significant change at all in Group B – Placebo, indicating that placebo treatment was ineffective objectively, in the treatment of metatarsalgia.

Group A – CMT only responded significantly later on in the treatment program (i.e. third to final consultation) and from the treatment overall (i.e. first to final consultation). This applied to both the Pain Threshold and Pain Tolerance readings. The evidence suggests that the experimental group’s treatment protocol was more effective in the treatment of metatarsalgia.

5.5 DISCUSSION

5.5.1 INTER-GROUP HYPOTHESIS

It was hypothesised that there would be a significant difference between the two groups with respect to the subjective and objective clinical findings, showing that foot and ankle adjustments (Chiropractic Manipulative Therapy – CMT) was effective in the treatment of primary metatarsalgia.

When comparing Group A – CMT with Group B – Placebo, in terms of subjective measurements, the two groups differed significantly with respect to the sensory
perception of pain (SF-MPQ) throughout the treatment period (Figure 1). Clinically, Group A – CMT was less affected than Group B – Placebo at the commencement of the program, and responded more favourably to the treatment protocol (Figure 1).

The two groups differed in terms of their perception of their Worst Pain at the beginning of the study, but were similar at the completion of the study (Figure 2.1). However, in terms of their perception of Least Pain, the two groups were similar at the start of the study, but there was a statistically significant difference between the second, third and final visits, indicating a fairly rapid response to the treatment protocol in Group A (Figure 2.1).

In terms of foot pain, disability and function, none of the patients responded negatively to the two questions in subscale 3 (of the Foot Function Index), indicating that none of them were immobilised by their condition. The two groups were similar at the beginning of the study, in terms of their response to the FFI-P (pain) and FFI-D (disability) (Table 4 and Figure 3.1). A statistically significant difference developed between the groups, in terms of the FFI-P, from the second visit onwards (Tables 5, 6 and 7, and Figure 3.1). FFI-D responses only differed significantly at the final consultation (Tables 4, 5, 6 and 7, and Figure 3.2).

The objective measurements, in terms of both pain threshold and pain tolerance, show no significant statistical difference between the two groups during the initial, second and third visits. There was no statistically significant difference for pain threshold
between the two groups at the final visit, but there was for pain tolerance (Tables 8, 9, 10 and 11).

5.5.2 INTRA-GROUP HYPOTHESIS

It was hypothesised that there would be a significantly greater improvement in Group A – CMT than in Group B – Placebo between the following consultations: initial and second, second and third, third and final and initial and final, in terms of subjective and objective clinical findings. This would show that Group A – CMT was more effective than placebo treatment in the management of primary metatarsalgia.

When comparing the first and second, and second and third consultations, there was a significant statistical difference in Group A – CMT, but not Group B – Placebo, in terms of subjective measurements. The only exception being between the second and third consultations, in Group B – Placebo, where there was a significant difference in terms of perception of foot pain (FFI-P). There was no significant statistical improvement in either group, in terms of objective readings, between the first and second, and second and third consultations. (Tables12.1, 12.2, 12.3, 13.1, 13.2, 13.3, 14, 15, 18, 19, 22, 23, 26 and 27).

Between the third and final consultations, there was significant statistical improvement in Group A – CMT, in terms of subjective and objective measurements (Tables12.1, 12.2, 12.3, 16, and 24). The exception was that there was no significant improvement in terms of patient perception of Least Pain, in Group A – CMT,
between these consultations. In Group B – Placebo, the only statistically significant
difference in terms of subjective and objective measurements between these
consultations, was the patients' perception of their Worst Pain (Tables13.1, 13.2, 13.3,
20, and 28).

When comparing the initial and final consultations, all the subjective and objective
measurements were found to have a significant statistical difference in Group A –
CMT (Tables12.1, 12.2, 12.3, 17, and 25). All the subjective measurements in Group
B – Placebo were found to differ significantly, in the comparison between the initial
and final consultations, except for the perception of Least Pain (Tables13.1, 13.2,
13.3, 21, and 29). However, there was no significant statistical difference in the
objective measurements between these two visits, in Group B – Placebo.

5.6 CONCLUSIONS

In conclusion, primary metatarsalgia responded more rapidly to CMT than to placebo
treatment, in terms subjective measurements. Primary metatarsalgia also responded
statistically significantly to CMT, in terms of objective measurements. Placebo
treatment resulted in no significant statistical objective improvement.

The author believes it is, however, very important to note that Group B – Placebo’s
perception of pain was higher from the beginning of the study. This may have been
linked to Group B – Placebo’s average chronicity, which was 8.35 years (Table 2), as
opposed to a much shorter chronicity of the condition in Group A – CMT (3.54 years
Objective measurements may have also been faulty, for various reasons. The first reason is that human error may occur when recording calibrations and there is also the possible risk of incorrect user method. It is suggested that an independent examiner be

5.7 LIMITATIONS OF THE STUDY

There are a number of reasons why the subjective measures may have had their limitations in terms of the condition being treated and the treatment protocol being administered.

The first limitation is that the questionnaires used in this study were not specifically designed for the study. In future studies on primary metatarsalgia, questionnaires specifically designed to relate to this condition should be used. Many of the subjects felt the questionnaires did not adequately cover aspects of their condition, for example some shoes aggravated the condition more than others.

The second limitation is the possible misunderstanding of the questionnaires by the patients, which may have affected their response and in turn, the outcome of the results. Patients may have recorded improvements beyond those actually felt to please the researcher.

Objective measurements may have also been faulty, for various reasons. The first reason is that human error may occur when recording calibrations and there is also the possible risk of incorrect user method. It is suggested that an independent examiner be
included to ensure the correct calibration of the equipment and the correct recording of the measurements.

It is important to note that using detuned ultrasound as a placebo form of treatment may have caused a weakness in the study, as it involves proprioception, which may affect the pain pathways. Possibly a better form of placebo could be a sugar tablet, which would eliminate the proprioceptive pathways.

A larger sample size may result in a stronger statistical difference between the two groups.

This randomised, placebo-controlled trial on metatarsalgia was a pilot study and as a result, has weaknesses which can be improved upon to strengthen the results: these are mentioned above.

5.8 COMPARISON OF THE RESULTS WITH OTHER STUDIES

As there are no randomised, placebo-controlled trials of a specific modality in the treatment of primary metatarsalgia, the closest comparable study was by Brantingham et al. (1994). This study investigated the effect of foot manipulation in the management of Morton's neuroma. Eighty-three percent of the patients had moderate to excellent relief of pain. The study was not placebo-controlled and the sample size was small, at twenty-nine patients. Twenty-three of these patients also received
orthotics, as part of their treatment, and a few had low-dye taping. In the author’s opinion, the reliability of the results is decreased because of the multiple treatment modalities used in the study.

The study by Brantingham et al. (1994) was used for the extrapolation of this study on metatarsalgia, because of the similarity of the conditions, and a lack of controlled trials for metatarsalgia. Similarities that were found between the two were: the conditions affected the older age group (over forty years), the prevalence of the conditions in females more than males (20 Morton’s neuroma patients out of 29, and 26 metatarsalgia patients out of 40), and the chronicity of the conditions (average 19 months for Morton’s neuroma, and average 5.95 years for metatarsalgia patients).

This study on primary metatarsalgia revealed the efficacy of foot and ankle manipulation in its management, and so does support the research by Brantingham et al. (1994).
CHAPTER SIX

RECOMMENDATIONS AND CONCLUSIONS

6.1 RECOMMENDATIONS

It is recommended that a larger sample size be used (e.g. thirty patients per group) for a more accurate statistical analysis, if the study is to be repeated.

It is recommended that the amount or grade of dysfunction be taken into account if the study is to be repeated. This is suggested as the Algometer readings and the questionnaires did not accurately reflect the marked increase in physical activity that the patients experienced as a result of CMT, and reported to the researcher.

The experience and reliability of the examiner and the accuracy of the measurement parameters do need to be considered. It is recommended that the use of an independent examiner be considered.

It is recommended that specific questionnaires relating to primary metatarsalgia be considered, so as to provide more accurate subjective data.

It is recommended that an alternative form of placebo be used, in the form of a placebo or “sugar” tablet, to eliminate the proprioceptive element of detuned ultrasound.
6.2 CONCLUSIONS

From the results of the analysis, primary metatarsalgia responded more rapidly to CMT than to placebo treatment, in terms subjective measurements. Primary metatarsalgia also responded statistically significantly to CMT, in terms of objective measurements. Placebo treatment resulted in no significant statistical objective improvements, although there was a significant subjective improvement overall.

Therefore, although both groups responded subjectively to their respective treatment protocols, Group B – Placebo’s response was more delayed. This could have been the result of the natural history of the disease, on which no literature could be found, the placebo effect or the proprioceptive effect of the ultrasound head on the skin. Only Group A – CMT responded objectively to the treatment.

It can be noted that subjectively and objectively, chiropractic foot and ankle manipulation appears to be a reliable intervention in the treatment of primary metatarsalgia, and also appears to be more effective than placebo.
REFERENCE LIST


APPENDIX 1: Case History

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: ________________________________ Date: ____________________
file #: __________ X-Ray#: ____________________
Age: ______ Sex: ______ Occupation: ____________________
Intern: ________________________________ Signature: ____________________

FOR CLINICIAN'S USE ONLY
Initial visit clinician: ____________________ Signature: ____________________

Case History:

Examination:
  Previous: ____________________________ Current: ____________________________

X-Ray Studies:
  Previous: ____________________________ Current: ____________________________

Clinical Path. lab:
  Previous: ____________________________ Current: ____________________________

Case Status:

PTT: Conditional: Signed Off: Final Sign out:

Recommendations:

Intern's Case History

1. Source of History:

2. Chief Complaint: (patient's own words)
3. Present Illness:
   - Location
   - Onset
   - Duration
   - Frequency
   - Pain (Character)
   - Progression
   - Aggravating Factors
   - Relieving Factors
   - Associated S & S
   - Previous Occurrences
   - Past Treatment and Outcome

4. Other Complaints:

5. Past Medical History:
   - General Health Status
   - Childhood Illnesses
   - Adult Illnesses
   - Psychiatric Illnesses
   - Accidents/Injuries
   - Surgery
   - Hospitalizations
6: Current health status and life-style:
- Allergies
- Immunizations
- Screening Tests
- Environmental Hazards (Home, School, Work)
- Safety Measures (seat belts, condoms)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
- Tobacco
- Alcohol
- Social Drugs

7. Immediate Family Medical History:
- Age
- Health
- Cause of Death
- DM
- Heart Disease
- TB
- Stroke
- Kidney Disease
- CA
- Arthritis
- Anaemia
- Headaches
- Thyroid Disease
- Epilepsy
- Mental Illness
- Alcoholism
- Drug Addiction
- Other
8. Psychosocial history:
   - Home Situation and daily life
   - Important experiences
   - Religious Beliefs

9. Review of Systems:
   - General
   - Skin
   - Head
   - Eyes
   - Ears
   - Nose/Sinuses
   - Mouth/Throat
   - Neck
   - Breasts
   - Respiratory
   - Cardiac
   - Gastro-intestinal
   - Urinary
   - Genital
   - Vascular
   - Musculoskeletal
   - Neurologic
   - Haematologic
   - Endocrine
   - Psychiatric
TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient: ___________________________ File#: ___________________________ Date: ____________
Clinician: ________________________ Signature: ___________________________
Intern: __________________________ Signature: ___________________________

1. VITALS

Pulse rate: ______________________
Respiratory rate: ______________________
Blood pressure: ______________________
Temperature: ______________________
Height: ______________________
Weight: ______________________

2. GENERAL EXAMINATION

General Impression: ______________________
Skin: ______________________
Jaundice: ______________________
Pallor: ______________________
Clubbing: ______________________
Cyanosis (Central/Peripheral): ______________________
Oedema: ______________________
Lymph nodes: ______________________
- Head and neck: ______________________
- Axillary: ______________________
- Epitrochlear: ______________________
- Inguinal: ______________________
Urinalysis: ______________________

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in Cardiac Failure?
2) Does this patient have signs of Infective Endocarditis?
3) Does this patient have Rheumatic Heart Disease?

Inspection: ______________________
- Scars: ______________________
- Chest deformity: ______________________
- Precordial bulge: ______________________
- Neck - JVP: ______________________

Palpation: ______________________
- Apex Beat (character + location): ______________________
- Right or left ventricular heave: ______________________
- Epigastric Pulsations: ______________________
- Palpable P2: ______________________
- Palpable A2: ______________________
Pulses:  
- General Impression:  
- Radio-femoral delay:  
- Carotid:  
- Radial:  
- Dorsalis pedis:  
- Posterior tibial:  
- Popliteal:  
- Femoral:  

Percussion:  
- borders of heart

Auscultation:  
- heart valves (mitral, aortic, tricuspid, pulmonary)  
- Murmurs (timing, systolic/diastolic, site, radiation, grade)

4. **RESPIRATORY EXAMINATION**

1) Is this patient in **Respiratory Distress**?

**Inspection**  
- Barrel chest:  
- Pectus carinatum/cavumatum:  
- Left precordial bulge:  
- Symmetry of movement:  
- Scars:

**Palpation**  
- Tracheal symmetry:  
- Tracheal tug:  
- Thyroid Gland:  
- Symmetry of movement (ant + post)  
- Tactile fremitus:

**Percussion**  
- Percussion note:  
- Cardiac dullness:  
- Liver dullness:

**Auscultation**  
- Normal breath sounds bilat.:  
- Adventitious sounds (crackles, wheezes, crepitations)  
- Pleural frictional rub:  
- Vocal resonance - Whispering pectoriloquy:  
  - Bronchophony:  
  - Egophony:

5. **ABDOMINAL EXAMINATION**

1) Is this patient in **Liver Failure**?

**Inspection**  
- Shape:  
- Scars:  
- Hernias:

**Palpation**  
- Superficial:  
- Deep = Organomegally:
- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

Auscultation - Bowel sounds:
- Arteries (aortic, renal, iliac, femoral, hepatic)

Rectal Examination - Perianal skin:
- Sphincter tone & S4 Dermatome:
- Obvious masses:
- Prostate:
- Appendix:

6. **G.U.T EXAMINATION**

External genitalia:
Hernias:
Masses:
Discharges:

7. **NEUROLOGICAL EXAMINATION**

Gait and Posture - Abnormalities in gait:
- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Romberg's test (Pronator Drift):

Higher Mental Function - Information and Vocabulary:
- Calculating ability:
- Abstract Thinking:

G.C.S.:
- Eyes:
- Motor:
- Verbal:

Evidence of head trauma:

Evidence of Meningism: - Neck mobility and Brudzinski's sign:
- Kernig's sign:

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

II External examination of eye:
- Visual Acuity:
- Visual fields by confrontation:
- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
   - Maxillary:
   - Mandibular:
 b. Motor - Masseter:
   - Jaw lateral movement:
 c. Reflexes - Corneal reflex
   - Jaw jerk

VI Lateral movement of eyes

VII a. Motor - Raise eyebrows:
   - Frown:
   - Close eyes against resistance:
   - Show teeth:
   - Blow out cheeks:
 b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function - Nystagmus:
   - Rombergs:
   - Wallenbergs:
Otoscope examination:

IX & Gag reflex:

X Uvula deviation:
Speech quality:

XI Shoulder lift:
S.C.M. strength:

XII Inspection of tongue (deviation):

Motor System:

a. Power
   - Shoulder = Abduction & Adduction:
   = Flexion & Extension:
   - Elbow = Flexion & Extension:
   - Wrist = Flexion & Extension:
- Forearm = Supination & Pronation
- Fingers = Extension (Interphalangeals & M.C P's)
- Thumb = Opposition
- Hip = Flexion & Extension
- Knee = Flexion & Extension
- Foot = Dorsiflexion & Plantar flexion
  = Inversion & Eversion
  = Toe (Plantarflexion & Dorsiflexion)

b. Tone
- Shoulder
- Elbow
- Wrist
- Lower limb - Int. & Ext. rotation
- Knee clonus
- ankle clonus

b. Reflexes
- Biceps
- Triceps
- Supinator
- Knee
- Ankle
- Abdominal
- Plantar

Sensory System:
a. Dermatomes
  - Light touch
  - Crude touch
  - Pain
  - Temperature
  - Two point discrimination

b. Joint position sense
  - Finger
  - Toe

c. Vibration
  - Big toe
  - Tibial tuberosity
  - ASIS
  - Interphalangeal Joint
  - Sternum

Cerebellar function:

Obvious signs of cerebellar dysfunction:
  = Intention Tremor
  = Nystagmus
  = Truncal Ataxia
Finger-nose test (Dysmetria):
Rapid alternating movements (Dysdiadochokinesia):
Heel-shin test:
Heel-toe gait:
Reflexes:
Signs of Parkinsons:

8. **SPINAL EXAMINATION**: (See Regional examination)

Obvious Abnormalities:
Spinous Percussion:
R.O.M:
Other:

9. **BREAST EXAMINATION**:

Summon female chaperon.

**Inspection**
- Hands rested in lap:
- Hands pressed on hips:
- Arms above head:
- Leaning forward:

**Palpation**
- masses:
- tenderness:
- axillary tail:
- nipple:
- regional lymph nodes:
## Foot and ankle regional examination

<table>
<thead>
<tr>
<th>Observation</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Gait analysis (antalgic limp, toe off, arch, foot alignment, tibial alignment).</td>
<td></td>
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<tr>
<td>Swelling</td>
<td></td>
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<tr>
<td>Heloma dura</td>
<td></td>
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<tr>
<td>Skin</td>
<td></td>
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<tr>
<td>Nails</td>
<td></td>
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<tr>
<td>Shoes</td>
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</tbody>
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### Active movements

<table>
<thead>
<tr>
<th>Movement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>weight bearing</td>
<td></td>
</tr>
<tr>
<td>Plantar flexion</td>
<td>50°</td>
</tr>
<tr>
<td>Dorsiflexion</td>
<td>20°</td>
</tr>
<tr>
<td>Supination</td>
<td></td>
</tr>
<tr>
<td>Pronation</td>
<td></td>
</tr>
<tr>
<td>Toe dorsiflexion</td>
<td>40° (mtp)</td>
</tr>
<tr>
<td>Toe plantar flexion</td>
<td>40° (mtp)</td>
</tr>
<tr>
<td>Big toe dorsiflexion (mtp) (65-70°)</td>
<td></td>
</tr>
<tr>
<td>Big toe plantar flexion (mtp) 45°</td>
<td></td>
</tr>
<tr>
<td>Toe abduction + adduction</td>
<td></td>
</tr>
<tr>
<td>5° first ray dorsiflexion</td>
<td></td>
</tr>
<tr>
<td>5° first ray plantar flexion</td>
<td></td>
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<tr>
<td>Non weight bearing</td>
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### Resisted Isometric movements:

<table>
<thead>
<tr>
<th>Movement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee flexion</td>
<td></td>
</tr>
<tr>
<td>Plantar flexion</td>
<td></td>
</tr>
<tr>
<td>Dorsiflexion</td>
<td></td>
</tr>
<tr>
<td>Supination (inversion)</td>
<td></td>
</tr>
<tr>
<td>Pronation (eversion)</td>
<td></td>
</tr>
<tr>
<td>Toe extension (dorsiflexion)</td>
<td></td>
</tr>
<tr>
<td>Toe flexion (plantar flexion)</td>
<td></td>
</tr>
</tbody>
</table>

### Passive movement motion palpation

<table>
<thead>
<tr>
<th>Joint</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle joint:</td>
<td>Plantarflexion, Dorsiflexion</td>
</tr>
<tr>
<td>Talocural:</td>
<td>Long axis distraction</td>
</tr>
<tr>
<td>Subtalar joint:</td>
<td>Varus, Valgus</td>
</tr>
<tr>
<td>First ray:</td>
<td>Dorsiflexion, Plantarflexion</td>
</tr>
</tbody>
</table>
Circumduction of forefoot on fixed rearfoot:
Midtarsal:  A-P glide   P-A glide  rotation
Tarso metatarsal joints: A-P
Intermetatarsal glide:
Metatarsophalangeal dorsiflexion (with associated plantar flexion of each toe)
Interphalangeal joints: long axis distraction  A-P glide
lat and med glide  rotation

Special tests
Anterior drawer test
Talar tilt
Thompson test
Homan sign
Tinel’s sign
Subtalar neutral position
Balance/proprioception
Test for rigid/flexible flatfoot

Alignment
Heel to ground
Feiss line
Tibial torsion
Heel to leg (subtalar neutral)
Forefoot to heel (subtalar & Midtarsal neutral)
First ray alignment
Digital deformities
Digital deformity flexible

Palpation
Anteriorly
Medial maleoli
Med tarsal bones, tibial (post) artery
Lat. malleolous, calcaneus, sinus tarsi, and cuboid bones
Inferior tib/fib joint, tibia, mm of leg
Anterior tibia, neck of talus, dorsalis pedis artery

Posteriorly
Calcaneus
Achilles tendon
Musculotendinous junction

Plantarily
Plantar muscles and fascia
Sesamoids
Dear Patient

Thank you for considering enrolling in this research programme. Outlined below is a brief explanation of what the research programme entails as well as what would be expected of you, the patient.

This research programme aims to compare the effect of two separate modalities used in the treatment of primary metatarsalgia or pain under the ball of the foot. If you choose to participate in this research programme you will undergo a full case history, physical and regional examination on your initial consultation. This will enable us to determine whether or not your complaint is due to primary metatarsalgia and therefore your eligibility for the programme. Further tests, x-rays of the foot, may be necessary to rule out certain conditions. A full time clinician is permanently on duty and will be there to assist should any problems arise.

Once it has been determined that you are a candidate for this research programme, you will be randomly assigned to one of two groups. One group will receive a sham treatment. You have a 50/50 chance of receiving this treatment. Neither procedure entails any risk to you. The programme will consist of two treatment sessions per week for a period four weeks and then a follow-up consultation one month later. You are expected to be present at all of these sessions.

If you should become pain free during the programme, you will still be expected to complete the programme to facilitate the collection of data. If you are on any medication or have to receive any medication or receive any other treatment during the course of the programme, please inform me. If you are on any medication, a twenty four hour washout period is required before you may be accepted on the research programme.

Please feel free to ask about any other concerns.

Shayan Petersen
(Chiropractic Intern)
INFORMED CONSENT FORM
( To be completed in duplicate by patient/subject )

Date: ______________________

Title of Research Project: __________________________________________

Name of Patient: __________________________________________

Name of Supervisor: __________________________________________

Name of Research Student: _______________________________________

Please circle the appropriate answer:

1. Have you read the research information sheet? Yes No
2. Have you had an opportunity to ask questions regarding this study? Yes No
3. Have you received satisfactory answers to your questions? Yes No
4. Have you had an opportunity to discuss this study? Yes No
5. Have you received enough information about this study? Yes No
6. Whom have you spoken to? ______________________________________
7. Do you understand the implications of your involvement in this study? Yes No
8. Do you understand that you are free to withdraw from this study? Yes No
   a) at any time Yes No
   b) without having to give any a reason for withdrawing, and Yes No
   c) without affecting your future health care. Yes No
9. Do you agree to voluntarily participate in this study Yes No

Please Print in block letters:

Patient/Subject Name: __________________________________ Signature: __________________________

Parent/Guardian Name: __________________________________ Signature: ________________________

Witness Name: __________________________________________ Signature: ________________________

Research Student Name: __________________________ Signature: ____________________________
APPENDIX 6: Short-form McGill Pain Questionnaire

SHORT-FORM MCGILL PAIN QUESTIONNAIRE (SF-MPQ)

Ronald Melzack

Patients Name: ___________________________ File #: _______ Date: _______

<table>
<thead>
<tr>
<th>SENSATION</th>
<th>NONE</th>
<th>MILD</th>
<th>MODERATE</th>
<th>SEVERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>THROBBING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>SHOOTING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>STABBING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>SHARP</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>CRAMPING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>GNAWING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>HOT-BURNING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>ACHING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>HEAVY</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>TENDER</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>SPLITTING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>TIRING-EXHAUSTING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>SICKENING</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>FEARFUL</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
<tr>
<td>PUNISHING-CRUZEL</td>
<td>0)</td>
<td>1)</td>
<td>2)</td>
<td>3)</td>
</tr>
</tbody>
</table>

APPENDIX 7: Numerical Pain Rating Scale

NUMERICAL PAIN RATING SCALE 101

PATIENT NAME: ___________________________  FILE NO.: ______________
DATE: ___________________________  TREATMENT NO.: ______________

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, when it is at its WORST. A zero (0) would mean “no pain at all” and one hundred (100) would mean “pain as bad as it could be”.

Please write only one number.

0 ___________________________  100

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, when it is at its LEAST. A zero (0) would mean “no pain at all” and one hundred (100) would mean “pain as bad as it could be”.

Please write only one number.

0 ___________________________  100

FOOT FUNCTION INDEX

INSTRUCTIONS: Please fill in a value somewhere between 0 and 10 describing your pain. 0 indicates no pain and 10 indicates the worst pain. If the question is not applicable then indicate this by writing N/A next to it.

Section A:

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morning pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain walking barefoot</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain walking with shoes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain standing with shoes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section B: Can you:

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk in the house</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk outside</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climb stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Descend stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stand on tip toe</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Get up from a chair</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climb curbs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section C: Do you have to:

<table>
<thead>
<tr>
<th></th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stay inside all day?</td>
<td></td>
</tr>
<tr>
<td>Stay in bed all day?</td>
<td></td>
</tr>
</tbody>
</table>

APPENDIX 9 A, B, C AND D: Algometer Readings and Instruction Booklet

**ALGOMETER READINGS**

Patient name : 
File no : 
Foot : 

<table>
<thead>
<tr>
<th>TREATMENT NUMBER</th>
<th>DATE</th>
<th>PAIN THRESHOLD</th>
<th>PAIN TOLERANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(8)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FORCE DIAL
CERTIFICATE OF CALIBRATION

WAGNER INSTRUMENTS certifies that all FORCE DIALS are calibrated at the factory to meet the specified accuracy of ±1% of full scale, advertised in our current catalog.

QUALITY CONTROL DIRECTOR

FORCE DIAL™
PUSH - PULL FORCE GAGE

MODELS FDK
FDZ
FDN

IMPORTANT INSTRUCTIONS
READ BEFORE USING
GENERAL

Your FORCÉ DIAL should not be used to measure forces below 25% of full scale since true accuracy is degraded as readings decrease from full scale. Before placing the FORCE DIAL into service it is also recommended to test for accuracy according to procedures found in the CALIBRATION section of this manual.

Model FDK FORCE DIALS have no zero on the dial, since setting the pointer at zero has no significance in calibration or accuracy; see CALIBRATION for details.

Lubrication of the FORCE DIAL is not recommended.

IMPORTANT

To prevent damage, keep an implement accessory on the plunger even when the piece is not in use and when using the pull hook. This provides a positive stop and prevents the plunger from being pushed too far.

CALIBRATION

The calibration of the FORCE DIAL may be checked by attaching the pull hook and suspending test weights at 1/4, 1/2, 3/4, and full capacity in the vertical position. The weight of the plunger, flat, tip and pull hook (.03 LB, 17/32 OZ, 15 G) should be subtracted from test results. If it is determined that recalibration is required the instrument should be returned to the factory.

IMPLEMENT WEIGHT ADJUSTMENT

The FORCE DIAL is calibrated for use in the horizontal position. When using low capacity models - thru 2 LB/.1000 G/.10 N - in the vertical position, add or deduct the weight of the implements used from your readings, as follows:

WEIGHT OF IMPLEMENTS:
- Plunger: .015 LB/.071 OZ/.017 G
- Flat Tip: .004 LB/.018 OZ/.004 G
- Long Rod: .009 LB/.05/32 OZ/.014 G
- Pull Hook: .013 LB/.07/32 OZ/.016 G

ADJUSTMENT:

<table>
<thead>
<tr>
<th>USE</th>
<th>WITH</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pushing Down</td>
<td>Plunger</td>
<td>.2 G</td>
</tr>
<tr>
<td>Pushing Down</td>
<td>Plunger/Flat Tip</td>
<td>.4 G</td>
</tr>
<tr>
<td>Pushing Down</td>
<td>Plunger/Long Rod</td>
<td>.4 G</td>
</tr>
<tr>
<td>Pulling Down</td>
<td>Plunger/Flat Tip</td>
<td>.4 G</td>
</tr>
<tr>
<td>Pulling Up</td>
<td>Plunger/Flat Tip</td>
<td>.4 G</td>
</tr>
<tr>
<td>Pulling Up</td>
<td>Plunger</td>
<td>.2 G</td>
</tr>
<tr>
<td>Pulling Up</td>
<td>Plunger/Flat Tip</td>
<td>.4 G</td>
</tr>
<tr>
<td>Pulling Up</td>
<td>Plunger/Flat Tip/ Hook</td>
<td>.8 G</td>
</tr>
</tbody>
</table>
Your FORCE DIAL may be mounted with three #8 (.138 in/3.5 mm O.D.) sheet metal screws using the hole pattern shown below. The three dimples on the rear housing will assist in starting the screws. Sturdy posts are located internally behind the dimples to accept the screws. The screws should penetrate no more than 3/8 inches or 10 mm.

**MOUNTING**

**PARTS**

1. Retainer  (5) Calibration  (6) Case  (7) Spring  
3. Disc  (5) Calibration  (9) Push Button  
4. Clip  (8) Case  (10) Crystal  

**ACCESSORIES:**

- Flat Tip (thru 2 Lb / 1000 G / 10 N)
- Flat Tip (5 Lb / 2500 G / 20 N & up)
- Long Rod (thru 2 Lb / 1000 G / 10 N)
- Long Rod (5 Lb / 2500 G / 20 N & up)
- Pull Hook (thru 2 Lb / 1000 G / 10 N)
- Pull Hook (5 Lb / 2500 G / 20 N & up)

For shown in diagram.

**DIMENSIONS**

High and low capacity models differ slightly in design. The lettered dimensions above, along with the corresponding measurements shown below, identify these small variations.

All dimensions are approximate:

<table>
<thead>
<tr>
<th>Low Capacity (thru 2 Lb / 1000 G)</th>
<th>High Capacity (5 Lb / 2500 G)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>19</td>
</tr>
<tr>
<td>B</td>
<td>12</td>
</tr>
<tr>
<td>C</td>
<td>M3</td>
</tr>
<tr>
<td>D</td>
<td>M3</td>
</tr>
<tr>
<td>E</td>
<td>M3</td>
</tr>
<tr>
<td>G</td>
<td>12</td>
</tr>
<tr>
<td>H</td>
<td>H-M3</td>
</tr>
<tr>
<td>J</td>
<td>2.8</td>
</tr>
<tr>
<td>K</td>
<td>1.9</td>
</tr>
</tbody>
</table>